Sunshine Act Meetings

Federal Register
Vol. 58, No. 202
Thursday, October 21, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 58 FR 52138, Wednesday, October 6, 1992.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 2:00 P.M. (Eastern Time) Tuesday, October 19, 1993.

CHANGE IN THE MEETING:

Closed Session

The closed portion of the meeting has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: Frances M. Hart, Executive Officer on (202) 663–4070.

Dated: October 19, 1993.

Frances M. Hart,

Executive Office, Executive Secretariat.

[FR Doc. 93–26090 Filed 10–19–93; 2:30 am]

BILLING CODE 6750–06–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:08 a.m. on Tuesday, October 19, 1993, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider (1) matters relating to the probable failure of an insured depository institution; (2) matters relating to the Corporation's corporate activities; and (3) a personnel matter.

In calling the meeting, the Board determined, on motion of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), seconded by Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by Acting Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550–17th Street, NW., Washington, DC.

Dated: October 19, 1993.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 93–26103 Filed 10–19–93; 3:25 pm]

BILLING CODE 6714–01–M

FEDERAL ELECTION COMMISSION

FEDERAL REGISTER NUMBER: 93–25398.

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, October 21, 1993, 10:00 a.m., Meeting Open to the Public.

THE FOLLOWING ITEM WAS DELETED FROM THE AGENDA: Briefing on REGO.

DATE AND TIME: Tuesday, October 26, 1993 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Wednesday, October 27, 1993 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This oral hearing will be open to the public.

MATTERS BEFORE THE COMMISSION: Federal Funding of Presidential Nominating Conventions (11 C.F.R. Parts 107, 114, and 9008).

DATE AND TIME: Thursday, October 28, 1993 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Advisory Opinion 1993–19: Charles F.C. Ruff on behalf of Friends of John Glenn.

Revised Final Ex Parte Communications Rules, with Statement of Basis and Purpose (continued from meeting of September 16, 1993).

Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Press Officer, Telephone: (202) 219–4155.

Delores Hardy,

Administrative Assistant.

[FR Doc. 93–26101 Filed 10–19–93; 3:24 pm]

BILLING CODE 6715–01–M

FEDERAL HOUSING FINANCE BOARD

TIME AND DATES: 9:00 a.m., Wednesday, October 27, 1993.

PLACE: Board Room Second Floor, Federal Housing Finance Board 1777 F Street, NW., Washington, DC 20006.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED

PORTIONS OPEN TO THE PUBLIC: The Board will consider the following:

1. FHLBank System Reports
   A. Monthly Financial Report
   B. Monthly Membership Report
   C. Third Quarter 1993 CIP Report
   D. Quarterly Office of Finance Report
2. Amendment of Affordable Housing Program and Community Support Requirements Regulations
3. Publication of the methodology to be used by the Finance Board in determining compliance with the Private Sector Adjustment Factor (PSAF) Pricing Requirements
4. Approval of three State Housing Finance Agencies as Eligible Nonmember Mortgagee Borrowers

PORTIONS CLOSED TO THE PUBLIC: The Board will consider the following:

1. Approval of the September Board Minutes
2. Key Issues to be Addressed in Revisions to AHP Regulations
3. FHLBank Presidents' Compensation Plan - 1994 salary ranges, grade designations and merit increase guidelines
4. Board Management Issues

The above matters are exempt under one or more of sections 552b(c)(6) and (9)(B) of title 5 of the United States Code.

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Executive Secretary to the Board, (202) 408–2837.

Philip L. Conover,

Managing Director.

[FR Doc. 93–26021 Filed 10–19–93; 12:02 pm]

BILLING CODE 6725–01–P

FEDERAL MARITIME COMMISSION

TIME AND DATE: 10:00 a.m.—October 27, 1993.

PLACE: Hearing Room One—800 North Capital St., NW., Washington, DC 20573–0001.

STATUS: Part of the meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTER(S) TO BE CONSIDERED:

Portion Open to the public:

1. Docket No. 92–31—*Service Contracts*—Consideration of Comments on Proposed Rule.

2. Docket No. 93–10—*Amendments to Rules Governing Rate Proceedings in the Domestic Offshore Trades*—Consideration of Comments on Proposed Rule.

Portion Closed to the public:

1. Docket No. 91–27—*American President Lines, Ltd. v. Cyprus Mines Corporation and Cyprus Minerals Company;* and

Docket No. 92–01—*American President Lines, Ltd. v. Cyprus Cooper Company and Cyprus Mineral Company*—Consideration of the Record.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523–5725.

Joseph C. Polking,

Secretary.

[FR Doc. 93–26100 Filed 10–19–93; 2:55 pm]

BILLING CODE 6730–01–M

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of October 18, 1993.

A closed meeting will be held on Wednesday, October 20, 1993, at 10:00 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Beese, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Wednesday, October 20, 1993, at 10:00 a.m., will be:

Institution of injunctive actions.

Settlement of injunctive actions.

Institution of administrative proceedings of an enforcement nature.

Settlement of administrative proceedings of an enforcement nature.

Regulatory matter regarding financial institutions.

Opinions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Bruce Rosenblum at (202) 272–2300.

Dated: October 15, 1993.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–26039 Filed 10–19–93; 8:45 am]

BILLING CODE 8010–01–M

Corrections

Federal Register
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This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

FEDERAL COMMUNICATIONS COMMISSION

Applications for Consolidated Hearing

Correction

In notice document 93-21597 appearing on page 47139 in the issue of Tuesday, September 7, 1993, in the second column, in the table, the MM Docket No. "93-421" should read "93-241".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-930-4210-04; N-57773]

Realty Action: Exchange of Public Lands in Clark County, Nevada

Correction

In notice document 93-22015, beginning on page 47472 in the issue of Thursday, September 9, 1993 make the following correction:

On page 47473, in the first column, in the third paragraph, in the sixth line, "for" should read "from".

BILLING CODE 1505-01-D

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32359]

Peninsula Corridor Joint Powers Board—Trackage Rights Exemption—Southern Pacific Transportation Co.; Exemption

Correction

In notice document 93-25086 appearing on page 52977 in the issue of Wednesday, October 13, 1993, the docket number should read as set forth above.

BILLING CODE 1505-01-D

federal register

Thursday
October 21, 1993

Part II

Department of the Interior

Bureau of Indian Affairs

25 CFR Part 11
Law and Order on Indian Reservations; Final Rule

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 11

RIN: 1076–AA01

Law and Order on Indian Reservations

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Indian Affairs (BIA) is revising its regulations governing Courts of Indian Offenses to provide those courts with a complete and updated code of laws, and to clarify the jurisdiction of those courts and their relationship to tribal governments and the Department of the Interior.

EFFECTIVE DATE: November 22, 1993.

FOR FURTHER INFORMATION CONTACT: Chief, Branch of Judicial Services, Bureau of Indian Affairs, 1849 C St., NW., Mail Stop 2611–MIB, Washington, DC 20240–4001, telephone number (202) 208–4400.

SUPPLEMENTARY INFORMATION: This rule is published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

Proposed regulations were published in the **Federal Register** on October 24, 1985 (50 FR 43235). The period of public comment closed on December 23, 1985. Numerous comments were received and reviewed. As a result, some changes were made as discussed in detail below.

Background and Need for Changes to Existing Regulations

Courts of Indian Offenses are established by the Department of the Interior in those areas of Indian country where tribes retain jurisdiction over Indians that is exclusive of state jurisdiction, but where the tribe has not established a tribal court to exercise that jurisdiction.

Although the rules of these courts are established and the judges appointed by the BIA, the regulations provide for substantial participation by tribal governments in their operation. For instance, the appointment and removal of judges is subject to tribal council action, and judges and tribal councils may supplement or supersede provisions in the regulations by adopting their own ordinances subject to the approval of the BIA.

While the United States Supreme Court has treated these courts as exercising tribal authority, *Williams* v. *Lee*, 358 U.S. 217, 222–223 (1959), it has expressly reserved the question of the extent to which these courts are to be regarded as Federal instrumentalities. *United States* v. *Wheeler*, 435 U.S. 313, 327 n.26 (1978). The Department of the Interior must, however, define for administrative purposes the effect of the decisions of Courts of Indian Offenses on its own decision-making process. Accordingly, the new rules provide that decisions of Courts of Indian Offenses will be given the same weight in decision-making by the Department of the Interior that is accorded to decisions by tribal courts (courts established by purely tribal action).

To further implement that concept, the rule explicitly states that decisions of a Court of Indian Offenses are appealable only to the appellate division of the Court of Indian Offenses, and that appellate division decisions are not subject to administrative appeals within the Department of the Interior. Additionally, jurisdiction over federal and state officials is limited to the jurisdiction a tribal court would have over such officials.

The term "Indian country" is used instead of "reservation" in describing the jurisdiction of Courts of Indian Offenses for consistency with federal jurisdictional statutes.

The present regulations contain a very incomplete criminal code that does not cover many areas of the law that are usually covered in the laws of the state where the reservation is located. The present regulations also contain very sketchy provisions on criminal and civil procedure. The regulations do provide, however, for the local tribal government to enact ordinances that will be enforced in, but apply only to, the tribe's Indian country. Many tribes have taken advantage of this provision to supplement the existing regulations extensively.

These new regulations update the sections on criminal offenses, and essentially create new sections on criminal procedure, domestic relations, probate proceedings, appellate proceedings, and juvenile proceedings.

The criminal procedure sections are largely derived from the draft model code which was prepared pursuant to Title III of the 1968 Civil Rights Act, 82 Stat. 73, 77–78 (codified at 25 U.S.C. 1311–1312). THe sections on criminal offenses are derived to a large extent from the Model Penal Code of the American Law Institute which has stimulated revision and codification of the substantive criminal law of the United States and of numerous states which have drawn upon the Model Code in their code revisions. However, some sections of the Model Code have been modified, and some eliminated totally according to the needs and particular circumstances of Courts of Indian Offenses. The sections on criminal offenses are divided into six important areas of penal law: (1) Offenses involving injury or danger to the person such as assault, reckless endangering, threats, false imprisonment and criminal coercion; (2) sexual offenses; (3) the major offenses against property including reckless burning, criminal mischief, theft, forgery, and fraudulent practices; (4) offenses against the family such as endangering child welfare, and persistent non-support; (5) offenses against public administration including bribery, corrupt influence, perjury and other falsification; (6) offenses against public order such as disorderly conduct, riot, harassment, carrying concealed weapons, and others. In addition, it is provided that violations of duly enacted tribal ordinances are punishable as provided for in the ordinance.

Crimes under this part have been divided in three groups: Misdemeanors, petty misdemeanors, and violations. Felonies that are covered by the Major Crimes Act are excluded in order to avoid the possibility that someone who has committed a serious offense may be immunized from federal prosecution because of the prohibition against double jeopardy by a prosecution in a Court of Indian Offenses where the maximum penalty is limited by the Indian Civil Rights Act, 25 U.S.C. 1302(7).

The sections on gambling and game violations have been deleted because these violations are covered by § 11.449, violation of an approved tribal ordinance.

Sections on civil actions remain essentially unchanged from the proposal. However, § 11.503 provides for the applicability of the Federal Rules of Civil Procedure to Courts of Indian Offenses.

The sections on domestic relations have been expanded to provide better guidance to the courts in dealing with such matters. These sections are derived from the Uniform Marriage and Divorce Act, with minor modifications. Similarly, sections on probate proceedings have also been expanded. Sections on appellate proceedings have been expanded to provide basic appeal procedures which do not exist under the present code.

New sections creating a children's court have also been developed. These sections are divided into three parts: A general section dealing with definitions, personnel, and jurisdiction; sections dealing with juvenile offender procedure; and sections dealing with

minor-in-need-of-care procedure. These sections are based on the Model Children's Code that was developed by the American Indian Law Center in Albuquerque, New Mexico. These sections supplant 25 CFR 11.36 which is inadequate to address the role of the courts in dealing with juvenile problems.

Sections 11.6C, 11.7C, 11.20C, 11.22C, 11.24C, 11.26C, 11.29C, 11.31C, 11.32C, 11.34C, 11.36C, 11.50C, 11.60C, 11.63C, 11.64C, and 11.75C have been removed because the Crow Tribe has converted their Court of Indian Offense into a tribal court. For similar reasons, §§ 11.50ME, 11.55ME, 11.70ME, and §§ 11.88ME–11.98ME pertaining to the Menominee Tribe are also deleted. In addition, §§ 11.76H to 11.87H are deleted because these regulations pertain to the Hopi Tribe and should be enforced in the Hopi Tribal Court.

The Omaha Tribe is deleted from the listing of Courts of Indian Offenses under § 11.100(a) because it has converted their Court of Indian Offenses into a tribal court.

As is presently the case, courts will be established or abolished through the Federal rulemaking procedure by adding or deleting the name of a tribe from the list. The BIA will continue to assist tribes with Courts of Indian Offenses to develop their own codes and convert to tribal courts. It is the BIA's policy to encourage the replacement of Courts of Indian Offenses with tribal courts.

A new section has been added to make it clear that changes in the regulations do not affect criminal or civil liability for actions that occurred prior to the effective date of the change.

This final rule is not made effective until 30 days after its publication in the Federal Register.

Clarifications

The final rule includes various clarifications to the proposed rule which have been made principally in response to recommendations of commentators. Many of the clarifications address specific recommendations that certain text be revised to remove unclear or confusing language as noted in specific comments. With a few exceptions, these clarifications have not been individually discussed below, as the reasons for the clarifications become self-evident simply by comparing the text of the clarified rule with the corresponding proposed rule text. Certain clarifications have also been made to make the text consistent with the text of various substantive changes which are discussed below.

Analysis of Comments and Changes Made to Proposed Regulations

Section 11.100 Listing of Courts of Indian Offenses

Several comments questioned why the Osage Tribe was excluded from the list of tribes within the jurisdiction of the Court of Indian Offenses for tribes located in the former Oklahoma Territory. The Osage Tribe is not included because there has been no determination that a Court of Indian Offenses should be established to serve that tribe, nor has the Osage Tribal Council requested that a Court of Indian Offenses be set up to serve the Tribe.

Several comments suggested that § 11.100(a)(18) be amended to list those Oklahoma tribes which are served by the intertribal Court of Indian Offenses located there. This recommendation was adopted.

One comment recommended deletion of Secretarial approval of tribal ordinances under § 11.100(e). This recommendation was not adopted because Courts of Indian Offenses are Federal instrumentalities, and as such, the laws they enforce cannot be inconsistent with Federal law. Secretarial approval of tribal ordinances under § 11.100(e) is necessary to ensure such compliance.

Section 11.102 Criminal Jurisdiction; Limitation of Actions

Pursuant to a comment, this section was amended by adding a new subsection (b) to provide that a criminal prosecution is barred unless it is instituted by the filing of a complaint within five years of the commission of the offense. The five-year limitation period is similar in length to those found in federal statutes of limitations applicable to the prosecution of federal offenses. This section has been retitled to reflect this modification.

Section 11.103 Civil Jurisdiction; Limitation of Actions

As with the criminal jurisdiction section, this section has been amended to include a three-year limitation period within which to file a civil action. This limitation period is similar in length to those found in numerous state statutes of limitations applicable in civil actions. This section has been retitled accordingly.

In addition, several comments recommended that this section be amended to permit Courts of Indian Offenses to acquire jurisdiction over lawsuits by Indian plaintiffs against non-Indian defendants absent stipulation by the parties. This recommendation has not been adopted. Although tribal court jurisdiction over non-Indians has been upheld by the U.S. Supreme Court under certain conditions, Courts of Indian offenses are not the equivalent of tribal courts, and the Federal Government is not disposed to unnecessarily expand the jurisdiction of its Courts of Indian Offenses.

Indian tribes served by Courts of Indian Offenses are authorized to create their own tribal court systems should they desire to assume additional jurisdiction.

Section 11.104 Jurisdictional Limitations

Several comments objected to the provision prohibiting Courts of Indian Offenses from adjudicating tribal government disputes absent a tribal council resolution or ordinance conferring such jurisdiction. They argue that these courts should be regarded as part of the tribal government and that resolution of such disputes by these courts is preferable to resolution by the BIA.

It is clear, however, that Courts of Indian Offenses are part of the Federal Government. *United States* v. *Red Lake Band of Chippewa Indians*, 827 F.2d 380, 383 (8th Cir. 1987), *cert. denied*, 108 S. Ct. 1109 (1988). Their involvement, without the consent of the tribal government, in tribal government disputes, is an unwarranted interference in tribal affairs. Unless the tribal government requests it, Court of Indian Offenses should not become a competing forum for those matters.

Although the BIA must occasionally decide who speaks for the tribe in order to carry out its responsibilities, it gives great weight to conclusions of the appropriate tribal forum when it does so. The use of the Court of Indian Offenses as such a forum would not affect the degree of involvement of other parts of the BIA in such matters.

One comment objected to the use of the term "tribal resolution" in §§ 11.104 (b) and (e) and recommended substituting the term "tribal ordinance". These provisions have been modified to provide tribes the option to choose between the two instruments.

Section 11.201 Appointment of Magistrates

Several comments objected to the role of the Assistant Secretary—Indian Affairs in appointing magistrates under § 11.201(a), or to his or her approval of judicial qualifications under § 11.201(e), and recommended only a tribal role in such decisions. These recommendations were not adopted because Courts of Indian Offenses are Federal instrumentalities and not tribal bodies.

Federal supervision is therefore mandatory.

Section 11.202 Removal of Magistrates

One comment objected to the role of the Assistant Secretary—Indian Affairs in removing magistrates, and recommended that the decision to remove a magistrate be left to the tribe or tribes affected. For the reasons stated above under § 11.201, this recommendation has not been adopted.

Section 11.203 Court Clerks

One comment suggested including a new subsection to provide for the disposition of moneys received on judgments. This recommendation has been adopted and incorporated as § 11.203(c).

Section 11.205 Standards Governing Appearance of Attorneys and Lay Counselors

Two comments objected to § 11.205(a) because it appears to conflict with a provision of the Indian Civil Rights Act (ICRA). Courts of Indian Offenses, however, are Federal instrumentalities and are bound not only by the ICRA, but by the requirements of the United States Constitution as well.

Section 11.206 Court Records

Two comments recommended adding a provision giving the magistrate discretion to seal certain court records. This recommendation has been adopted.

Section 11.207 Cooperation by Bureau of Indian Affairs Employees

In response to a comment, this section was expanded to provide for specific BIA assistance in the preparation and presentation of facts.

Section 11.300 Complaints

Some comments suggested that the signature of a complaining witness should not be required on a complaint, and that prosecutors should be allowed to file complaints independently. These recommendations were not adopted because it is felt that personal knowledge of the wrongful act must be a prerequisite to the filing of a complaint.

Section 11.301 Arrests

Several comments objected to § 11.301(b)(3) because it grants too much authority to an arresting officer, and is a rule that is not applicable to misdemeanors in most jurisdictions. This recommendation has been adopted and the subsection has been deleted.

Section 11.303 Notification of Rights at Time of Arrest

Several comments took exception to the requirement of notification of rights at the time of arrest, and suggested that a more appropriate time for such notification was prior to custodial interrogation. This recommendation has been adopted and the title of the section changed accordingly.

Section 11.308 Commitments

Several comments recommended amending this section to increase the time for detention from the proposed 36 hours which was deemed unnecessarily short. This recommendation has been adopted and the time limit has been increased to 72 hours.

Section 11.311 Subpoenas

Two comments recommended that the clerk of court also be permitted to sign subpoenas, as is the case in most court systems. This recommendation was adopted. In addition, a comment recommended modifying § 11.311(d) to set a definite age for a person with whom a subpoena may be left to make it unnecessary for police officers to ascertain what is a "suitable age". This recommendation has also been adopted and the age limit has been set at 18 years of age or older.

Section 11.312 Witness Fees

Pursuant to a comment, this section was amended to reflect that only subpoenaed fact witnesses are covered under § 11.312(a).

Section 11.313 Trial Procedure

Several comments objected to § 11.313(b) on the grounds that rules of evidence are necessary. This recommendation has been adopted, and the subsection amended to provide that Federal Rules of Evidence shall be applicable in Courts of Indian Offenses except insofar as such rules are superseded by order of the court or by the existence of inconsistent tribal rules of evidence.

Section 11.314 Jury Trials

Several comments objected to the requirement in § 11.314(d) that verdicts must be unanimous, citing the difficulty to obtain such verdicts. These comments merit consideration. However, in *Burch* v. *Louisiana*, 441 U.S. 130 (1979), the Supreme Court held that conviction by a non-unanimous six-person jury in a state criminal trial for a non-petty offense violates the rights of an accused to trial by jury guaranteed by the Sixth and Fourteenth Amendments. Although jury trials in Courts of Indian Offenses for offenses with potential punishment of up to six months in jail are conducted, they cannot be compared to jury trials in state courts for non-petty offenses. However, the rationale of the Burch decision may still be applicable here because the IRCA requires jury trials for all offenses where imprisonment is sought. To resolve this problem, this section has been modified to provide for an eight-person jury, six of whom must concur to render a verdict.

One comment recommended the alternative use of an advisory jury composed of reservation elders. This recommendation has not been adopted because it is felt that the use of such juries depends on tribal custom and may be implemented by individual tribes through specific tribal ordinances.

Section 11.315 Sentencing

One comment recommended clarification of this section to make it clear that a criminal defendant may be sentence and/or fined for each offense for the violation of multiple offenses of the same section of the Code of Criminal Offenses. This recommendation has not been adopted because it is quite clear that such sentencing is permissible under the regulation.

Section 11.316 Probation

Two comments recommended increasing the potential probation period to one year for all crimes as a deterrent to criminal activity. This recommendation has been adopted.

Section 11.318 Extradition

One comment recommended that Courts of Indian Offenses only honor extradition requests of jurisdictions that honor theirs. This recommendation has not been adopted because it is too inflexible.

Section 11.400 Assault

One comment recommended defining the term "physical menace" to avoid proof problems. This recommendation has not been adopted because that term has been defined by case law.

Section 11.406 Criminal Coercion

One comment recommended deletion of proposed § 11.406(a)(3) because it is vague and over broad. This recommendation has been adopted.

Section 11.407 Sexual Assault

One comment recommended modification of § 11.407(b) to recognize the varied contexts within which sexual abuse may occur. This recommendation has been adopted and the subsection modified by expanding the definition of sexual contact.

Section 11.408 Indecent Exposure

One comment noted that it is difficult for a prosecutor to prove motivation and recommended deletion of the motivation clause under this section. This recommendation has been adopted.

Section 11.424 Neglect of Children

Pursuant to a comment, this section has been modified and retitled to include a new subsection on compulsory school attendance which was omitted from the proposed rule through oversight. The present regulations do contain such a provision.

Section 11.445 Driving Violations

Several comments asked that this provision be modified to provide that the offense of driving while intoxicated be included independently of the offense of reckless driving. This suggestion has been adopted.

In addition, numerous comments noted the absence of a traffic code and recommended that one be included in these regulations. This section has been redrafted to provide for the applicability of state traffic laws in the absence of a tribal traffic code. The section's title has been modified accordingly.

Section 11.450 Maximum Fines and Sentences of Imprisonment

Since the publication of the proposed rule, the ICRA, 25 U.S.C. 1302(7) has been amended by Pub. L. 99–570, Title IV, section 4217, Oct. 27, 1986, 100 Stat. 3207–146, increasing penalty and punishment for any one offense from a term of six months or a fine of $500.00 to a term of one year and a fine of $5,000.00. The rule was not modified to reflect the increased penalty and punishment authorized under the ICRA.

Section 11.502 Cost in Civil Actions

One comment noted that the provision authorizing the court to require a complainant to place a deposit with the clerk of the court to cover costs may restrict access to the courts by those with legitimate claims. This recommendation has not been adopted because the provision is not mandatory and affords the court flexibility to control the filing of frivolous complaints.

Section 11.504 Applicable Rules of Evidence

Pursuant to comments similar to those offered under § 11.313, this section has been amended to provide for the general applicability of the Federal Rules of Evidence.

Section 11.600 Marriages

One comment suggested increasing the time for recording traditional marriages with the clerk of the court. This recommendation has been adopted and § 11.600(b)(2) has been modified to increase the recordation time to thirty days.

One comment noted that tribal law should be referenced under § 11.600(c)(6) since some tribes may have their own health laws on the subject. This recommendation has been adopted.

One comment requested the inclusion of a form for marriage license applications. This recommendation has been adopted.

Section 11.603 Invalid or Prohibited Marriages

Two comments objected to this section on the grounds that it may contravene tribal customs or represent an attempt to legislate morality. This recommendation has not been adopted because Indian tribes are authorized to adopt tribal ordinances superseding these regulations if a conflict exists.

One comment noted that in *Israel* v. *Allen*, 577 P.2d 762 (1978), the Colorado Supreme Court struck down as unconstitutional a Colorado statute prohibiting marriages between adoptive brothers and sisters. Section 11.603(a)(3) has been amended to comply with this decision.

Section 11.606 Dissolution Proceedings

One comment objected to the need to verify the petition or response, and recommended instead that one party should be required to appear and testify as to the prima facie case for divorce even if the other party defaults. This recommendation has not been adopted because it is felt that verification secures the accountability of the petitioners or parties.

Section 11.608 Final Decree; Disposition of Property; Maintenance; Child Support; Custody

Pursuant to a comment, § 11.600(b)(1) has been amended to clarify that Courts of Indian Offenses do not have the authority to divide trust assets.

One comment recommended more comprehensive child support procedures to include wage withholding, reciprocal enforcement of child support orders, and collection of past-due support from Federal tax refunds. This recommendation has been adopted.

Section 11.609 Determination of Paternity and Support

Pursuant to a comment, this section has been modified to include a new subsection conferring standing to bring an action under this section to any person or agency who has provided support or assistance to a minor.

Section 11.803 Record on Appeal

The deadline for the clerk's certification of the record has been extended to 20 days pursuant to a comment that the proposed five-day period was unrealistically short.

Subpart G Probate Proceedings

One comment noted that the proposed regulations under this subpart were too restrictive and may infringe on some tribal customs of descent and distribution. This comment has not been adopted because the regulations defer to tribal customs in the area of descent and distribution.

Section 11.900 Definitions

Several comments recommended shortening the two-year period under the definition of the word "abandon" to one year because of permanency concerns. This recommendation has been adopted.

Several comments recommended including a definition of either "status offense" or "status offender", and amending the definition of "minor-in-need-of-care" to include a minor who has been committing status offenses. This recommendation has been adopted.

Section 11.904 Guardian Ad Litem

One comment suggested amending this section to provide for the appointment of a guardian ad litem where the parent, guardian, or custodian has been accused of abusing or neglecting the child. This recommendation has been adopted.

Section 11.906 Rights of Parties

One comment suggested amending this provision to require the court to appoint counsel for the minor where there is a potential conflict of interest between the minor and his or her parents, guardian, or custodian. This recommendation has been adopted because the legal interests of the child often do not coincide with those of the parents.

Section 11.907 Transfer to Court of Indian Offenses

One comment complained of the relative short deadline in § 11.907(b)(1) in which to hold a transfer hearing to determine whether to transfer a case to the Court of Indian Offenses, as well as

other deadlines under this subpart, on the grounds that unrealistic or unnecessarily short deadlines are not in the interest of either the court or the minor. This recommendation has been adopted, and the following modifications were made to certain deadlines under this subpart: (1) The ten-day deadline in § 11.907(b)(1) has been extended to 30 days; (2) the ten-day deadline in § 11.1008 has been extended to 15 days; (3) the ten-day deadline in § 11.1011(a) has been extended to 15 days; (4) the ten-day deadline in § 11.1108(a) has been extended to 15 days; (5) the ten-day deadline in § 11.1111(a) has been extended to 15 days; and (6) the five-day deadline in § 11.1114(c) has been extended to 15 days.

Section 11.1000 Complaint

Pursuant to a comment, this section has been amended to permit the presenting officer to also file a complaint. Section 11.1100 has been similarly amended.

Section 11.1004 Detention and Shelter Care

Several comments recommended deleting the requirement that detention facilities be located on the reservation because of a potential lack of such facilities on some reservations. This recommendation has been adopted.

One comment recommended a clarification of what is "adequate supervision" under § 11.1004(b). This recommendation has been adopted and the term defined to mean that routine inspection of the room where the minor is housed is conducted every 30 minutes to assure his or her safety and welfare. A similar provisions was inserted under § 11.1104(b).

Section 11.1005 Preliminary Inquiry

One comment objected to the 24-hour deadline for preliminary inquiries in § 11.1005(a) as being too short. This recommendation has not been adopted because it is unreasonable to hold minors in detention without a prompt preliminary inquiry.

Section 11.1009 Summons

One comment suggested deleting the provision in § 11.1009(d) permitting delivery of a summons by publication to protect the child's privacy rights. This recommendation has been adopted. For the same reasons, the same provision has been deleted from § 11.1109 and § 11.1113(e)(4).

Section 11.1012 Dispositional Alternatives

One comment suggested that restitution by the minor be allowed as a dispositional alternative. This recommendation has been adopted.

Section 11.1104 Shelter Care

One comment objected to the provision in § 11.1104(b) permitting minors-in-need-of-care to be detained in the same facility as juvenile offenders. Although commendable, this recommendation is not adopted because of the relative shortage of such facilities on or near Indian reservations.

Section 11.1108 Date of Hearing

Pursuant to a comment, this provision has been modified to permit the refiling of a petition to protect the interest of the child.

Section 11.1112 Dispositional Alternatives

One comment recommended that only the presenting officer be permitted to recommend that termination proceedings be initiated, and that the magistrate should not be allowed to make such a recommendation and then proceed to determine it. This recommendation has been adopted and proposed § 11.1112(a)(6) has been deleted.

One comment urged that this section be modified to emphasize that efforts must be made to permit a minor to return or remain in his or her home. This recommendation has been adopted and the section modified accordingly.

One comment recommended adding a new subsection to provide for a permanency hearing within 18 months of the original placement. This recommendation has also been adopted.

Section 11.1114 Termination

One comment recommended a modification to this section to emphasize that reasonable efforts must be made to prevent removal of the minor from his or her home. This recommendation has been adopted.

One comment suggested that it should not be the function of the magistrate to review the petition until the parties have had an opportunity to be heard. This recommendation has been adopted and proposed § 11.1114(c) was deleted. The lettering of the subsections have been changed accordingly.

One comment objected to excusing the parents from testifying. The suggestion that parents should be forced to testify has not been adopted because the right against self-incrimination is not limited to criminal proceedings.

One comment noted that adoption procedures should be included in these regulations. Although this section provides that the Court of Indian Offenses must follow tribal adoption procedures, this section has been amended to provide that in the absence of such tribal procedures, state adoption procedures shall apply.

Evaluation and Certification

The Department of the Interior has determined that this document is not a major rule under the criteria established by Executive Order 12291 and does not have a significant economic effect on a substantial number of small entities under the criteria established by the Regulatory Flexibility Act. The intended effect of this rule is to update the sections under 25 CFR part 11 to provide Courts of Indian Offenses with a more complete set of rules. The proposed revision will not require additional staffing for these courts. It is not anticipated that this revision will have any effect on the annual caseload of these courts because it does not enlarge their jurisdiction, but mandates procedural guarantees. While it is true that some criminal provisions such as issuance of bad checks and defrauding secured creditors have been added, others, such as giving venereal disease to another and illicit cohabitation have been deleted, so that the net effect on caseload is going to be negligible. Courts of Indian Offenses are funded in their entirety by the Federal Government and do not receive additional funding from tribal governments. Because we do not foresee any economic effect on Courts of Indian Offenses as a result of this revision, there will be no requirement of additional outlays by the Federal Government or the tribes affected by the proposed revision.

The Department of the Interior has certified to the Office of Management and Budget that this final rule meets the applicable standards provided in sections 2(a) and 2(b) of Executive Order 12778.

In accordance with Executive Order 12630, the Department has determined that this final rule does not have significant takings implications.

The Department has also determined that this final rule does not have significant federalism effects.

The information collection requirements contained in § 11.600 and § 11.606 have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*, and assigned approval number 1076–0094. The information is being collected to obtain a marriage license (§ 11.600) and a divorce decree (§ 11.606) from the

Courts of Indian Offenses, and will be used by the courts to issue a marriage license or divorce decree. Response to this request is required to obtain a benefit.

Public reporting for this information collection is estimated to average .25 hours per response, including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the information collection. Direct comments regarding the burden estimate or any other aspect of this information collection to the Bureau of Indian Affairs, Information Collection Clearance Officer, Room 336–SIB, 1849 C Street, NW., Washington, DC 20240; and the Office of Information and Regulatory Affairs (Project 1076–0094), Office of Management and Budget, Washington, DC 20502.

Drafting Information

The primary author of this document is George T. Skibine, Office of the Solicitor, Division of Indian Affairs, Department of the Interior.

List of Subjects in

25 CFR Part 11

Courts, Indians—law, law enforcement and penalties.

25 CFR Part 12

Indians, Law enforcement, Police, and detention programs.

For the reasons given in the preamble, title 25, chapter I of the Code of Federal Regulations is amended as set forth below.

§§ 11.301–11.306 [Redesignation as 12.100–12.105 in New Part 12]

1. Part 11 is amended by redesignating §§ 11.301 through 11.306 as §§ 12.100 through 12.105 of a new Part 12, The Indian Police.

2. Part 11 is revised to read as follows:

PART 11—LAW AND ORDER ON INDIAN RESERVATIONS

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Authority: 5 U.S.C. 301; R.S. 463, 25 U.S.C. 2; R.S. 465, 25 U.S.C. 9; 42 Stat. 208, 25 U.S.C. 13; 38 Stat. 586, 25 U.S.C. 200.

Subpart A—Application; Jurisdiction

§ 11.100 Listing of Courts of Indian Offenses.

(a) Except as otherwise provided in this title, the regulations under this part are applicable to the Indian country (as defined in 18 U.S.C. 1151) occupied by the following tribes:

(1) Flandreau Santee Sioux Tribe (South Dakota).

(2) Yankton Sioux Tribe (South Dakota).

(3) Shoshone and Arapahoe Tribes of the Wind River Reservation (Wyoming).

(4) Bois Forte Band of the Minnesota Chippewa Tribe (Minnesota).

(5) Red Lake Band of Chippewa Indians (Minnesota).

(6) Cocopah Tribe (Arizona).

(7) Kaibab Band of Paiute Indians (Arizona).

(8) Paiute Shoshone Tribe of the Fallon Reservation and Colony (Nevada).

(9) Confederated Tribes of the Goshute Reservation (Nevada).

(10) Lovelock Paiute Tribe (Nevada).

(11) Te-Moak Band of Western Shoshone Indians (Nevada).

(12) Yomba Shoshone Tribe (Nevada).

(13) Duckwater Shoshone Tribe (Nevada).

(14) Kootenai Tribe (Idaho).

(15) Shoalwater Bay Tribe (Washington).

(16) Eastern Band of Cherokee Indians (North Carolina).

(17) Mississippi Band of Choctaw Indians (Mississippi).

(18) For the following tribes located in the former Oklahoma Territory (Oklahoma):

Absentee Shawnee Tribe of Indians of Oklahoma
Apache Tribe of Oklahoma
Caddo Tribe of Oklahoma
Cheyenne-Arapaho Tribes of Oklahoma
Citizen Band of Potawatomi Indians of Oklahoma
Comanche Tribe of Oklahoma (except Comanche Children's Court)
Delaware Tribe of Western Oklahoma
Fort Sill Apache Tribe of Oklahoma
Kaw Tribe of Oklahoma
Iowa Tribe of Oklahoma
Kickapoo Tribe of Oklahoma
Kiowa Tribe of Oklahoma
Otoe-Missouria Tribe of Oklahoma
Pawnee Tribe of Oklahoma
Tonkawa Tribe of Oklahoma
Wichita and Affiliated Tribes of Oklahoma

(19) Hoopa Valley Tribe, Yurok Tribe, and Coast Indian Community of California (California) (Jurisdiction limited to special fishing regulations).

(20) Louisiana Area (Includes Coushatta and other tribes in the State of Louisiana which occupy Indian country and which accept the application of this part; *Provided* that this part shall not apply to any Louisiana tribe other than the Coushatta Tribe until notice of such application has been published in the **Federal Register**).

(b) It is the purpose of the regulations in this part to provide adequate machinery for the administration of justice for Indian tribes in those areas of Indian country where tribes retain jurisdiction over Indians that is exclusive of state jurisdiction but where tribal courts have not been established to exercise that jurisdiction.

(c) The regulations in this part shall continue to apply to tribes listed under § 11.100(a) until a law and order code which includes the establishment of a court system has been adopted by the tribe in accordance with its constitution and by-laws or other governing documents, has become effective, and the Assistant Secretary—Indian Affairs or his or her designee has received a valid tribal enactment identifying the effective date of the code's implementation, and the name of the tribe has been deleted from the listing of Courts of Indian Offenses under § 11.100(a).

(d) For the purposes of the enforcement of the regulations in this part, an Indian is defined as a person who is a member of an Indian tribe which is recognized by the Federal Government as eligible for services from the BIA, and any other individual who is an "Indian" for purposes of 18 U.S.C. 1152–1153.

(e) The governing body of each tribe occupying the Indian country over which a Court of Indian Offenses has jurisdiction may enact ordinances which, when approved by the Assistant Secretary—Indian Affairs or his or her designee, shall be enforceable in the Court of Indian Offenses having jurisdiction over the Indian country occupied by that tribe, and shall supersede any conflicting regulation in this part.

(f) Each Court of Indian Offenses shall apply the customs of the tribe occupying the Indian country over which it has jurisdiction to the extent that they are consistent with the regulations of this part.

§ 11.101 Prospective application of regulations.

Civil and criminal causes of actions arising prior to the effective date of these regulations shall not abate but shall be determined in accordance with the regulations in effect at the time the cause arose.

§ 11.102 Criminal jurisdiction; limitation of actions.

(a) Except as otherwise provided in this title, each Court of Indian Offenses shall have jurisdiction over any action by an Indian (hereafter referred to as person) that is made a criminal offense under this part and that occurred within the Indian country subject to the court's jurisdiction.

(b) No person shall be prosecuted, tried or punished for any offense unless the complaint is filed within five years after such offense shall have been committed.

§ 11.103 Civil jurisdiction; limitation of actions.

(a) Except as otherwise provided in this title, each Court of Indian Offenses shall have jurisdiction over any civil action arising within the territorial jurisdiction of the court in which the defendant is an Indian, and of all other suits between Indians and non-Indians which are brought before the court by stipulation of the parties.

(b) Any civil action commenced in a Court of Indian Offenses shall be barred unless the complaint is filed within three years after the right of action first accrues.

§ 11.104 Jurisdictional limitations.

(a) No Court of Indian Offenses may exercise any jurisdiction over a Federal or state official that it could not exercise if it were a tribal court.

(b) Unless otherwise provided by a resolution or ordinance of the tribal governing body of the tribe occupying the Indian country over which a Court of Indian country over which a Court of Indian Offenses has jurisdiction, no Court of Indian Offenses may adjudicate an election dispute or take jurisdiction over a suit against the tribe or adjudicate any internal tribal government dispute.

(c) The decision of the BIA on who is a tribal official is binding in a Court of Indian Offenses.

(d) The Department of the Interior will accord the same weight to decisions of a Court of Indian Offenses that it accords to decisions of a tribal court.

(e) A tribe may not be sued in a Court of Indian Offenses unless its tribal governing body explicitly waives its tribal immunity by tribal resolution or ordinance.

Subpart B—Courts of Indian Offenses; Personnel; Administration

§ 11.200 Composition of court.

(a) Each court shall be composed of a trial division and an appellate division.

(b) A chief magistrate will be appointed for each court who will, in addition to other judicial duties, be responsible for the administration of the court and the supervision of all court personnel.

(c) Appeals shall be heard by a panel of three magistrates who were not involved in the trial of the case.

(d) Decisions of the appellate division are final and are not subject to administrative appeals within the Department of the Interior.

§ 11.201 Appointment of magistrates.

(a) Each magistrate shall be appointed by the Assistant Secretary—Indian Affairs or his or her designee subject to confirmation by a majority vote of the tribal governing body of the tribe occupying the Indian country over which the court has jurisdiction, or, in the case of multi-tribal courts, confirmation by a majority of the tribal governing bodies of the tribes under the jurisdiction of a Court of Indian Offenses.

(b) Each magistrate shall hold office for a period of four years, unless sooner removed for cause or by reason of the abolition of the office, but is eligible for reappointment.

(c) No person is eligible to serve as a magistrate of a Court of Indian Offenses who has ever been convicted of a felony or, within one year of the date of service or application, of a misdemeanor.

(d) No magistrate shall be qualified to act as such wherein he or she has any direct conflicting interest, real or apparent.

(e) A tribal governing body may set forth such other qualifications for magistrates of the Court of Indian Offenses as it deems appropriate, subject to the approval of the Assistant Secretary—Indian Affairs, or his or her designee.

(f) A tribal governing body may also recommend requirements for the training of magistrates of the Court of Indian Offenses to the Assistant Secretary—Indian Affairs.

§ 11.202 Removal of magistrates.

Any magistrate of a Court of Indian Offenses may be suspended, dismissed or removed by the Assistant Secretary—Indian Affairs, or his or her designee, for cause, upon the written recommendation of the tribal governing body, and, in the case of multi-tribal courts, upon the recommendation of a majority of the tribal governing bodies of the tribes under the jurisdiction of a Court of Indian Offenses, or pursuant to his or her own discretion.

§ 11.203 Court clerks.

(a) Except as may otherwise be provided in a contract with the tribe occupying the Indian country over which the court has jurisdiction, the chief magistrate shall appoint a clerk of court for the Court of Indian Offenses within his or her jurisdiction, subject to the superintendent's approval.

(b) The clerk shall render assistance to the court, to local law enforcement officers and to individual members of the tribe in the drafting of complaints, subpoenas, warrants, commitments, and other documents incidental to the functions of the court. The clerk shall also attend and keep a record of all proceedings of the court and manage all monies received by the court.

(c) The clerk of court shall forward any monies received on judgments due to the person, agency, or corporation to which entitled, within 30 days unless directed otherwise by a magistrate of the Court of Indian Offenses.

§ 11.204 Prosecutors.

Except as may otherwise be provided in a contract with the tribe occupying the Indian country over which the court has jurisdiction, the superintendent shall appoint a prosecutor for each Court of Indian Offenses within his or her jurisdiction.

§ 11.205 Standards governing appearance of attorneys and lay counselors.

(a) No defendant in a criminal proceeding shall be denied the right to counsel.

(b) The chief magistrate shall prescribe in writing standards governing the admission and practice in the Court of Indian Offenses of professional attorneys and lay counselors.

§ 11.206 Court records.

(a) Each Court of Indian Offenses shall keep a record of all proceedings of the court containing the title of the case, the names of the parties, the complaint, all pleadings, the names and addresses of all witnesses, the date of any hearing or trial, the name of any magistrate conducting such hearing or trial, the findings of the court or jury, the judgment and any other information the court determines is important to the case.

(b) The record in each case shall be available for inspection by the parties to the case.

(c) Except for cases in which a juvenile is a party or the subject of a proceeding, and for cases whose records have been sealed by the court, all case records shall be available for inspection by the public.

(d) Such court records are part of the records of the BIA agency having jurisdiction over the Indian country where the Court of Indian Offenses is located and shall be protected in accordance with 44 U.S.C. 3102.

§ 11.207 Cooperation by Bureau of Indian Affairs Employees.

(a) No employee of the BIA may obstruct, interfere with, or control the functions of any Court of Indian Offenses, or influence such functions in any manner except as permitted by Federal statutes or the regulations in this part or in response to a request for advice or information from the court.

(b) Employees of the BIA shall assist the court, upon its request, in the preparation and presentation of facts in the case and in the proper treatment of individual offenders.

§ 11.208 Payment of judgments from individual Indian money accounts.

(a) Any Court of Indian Offenses may make application to the superintendent who administers the individual Indian money account of a defendant who has failed to satisfy a money judgment from the court to obtain payment of the judgment from funds in the defendant's

account. The court shall certify the record of the case to the superintendent. If the superintendent so directs, the disbursing agent shall pay over to the injured party the amount of the judgment or such lesser amount as may be specified by the superintendent.

(b) A judgment of a Court of Indian Offenses shall be considered a lawful debt in all proceedings held by the Department of the Interior or by a Court of Indian Offenses to distribute decedents' estates.

§ 11.209 Disposition of fines.

All money fines imposed for the commission of an offense shall be in the nature of an assessment for the payment of designated court expenses. The fines assessed shall be paid over by the clerk of the court to the disbursing agent of the reservation for deposit as a "special deposit, court funds" to the disbursing agent's official credit in the Treasury of the United States. The disbursing agent shall withdraw such funds, in accordance with existing regulations, upon order of the clerk of the court signed by a judge of the court for the payment of specified expenses. The disbursing agent and the clerk of the court shall keep an account of all such deposits and withdrawals available for public inspection.

Subpart C—Criminal Procedure

§ 11.300 Complaints.

(a) A complaint is a written statement of the essential facts charging that a named individual(s) has committed a particular offense. All criminal prosecutions shall be initiated by a complaint filed with the court by a law enforcement officer and sworn to by a person having personal knowledge of the offense.

(b) Complaints shall contain:

(1) The signature of the complaining witness, or witnesses, sworn before a magistrate, a court clerk, a prosecutor, or any law enforcement officer.

(2) A written statement by the complaining witness or witnesses having personal knowledge of the violation, describing in ordinary language the nature of the offense committed including the time and place as nearly as may be ascertained.

(3) The name or description of the person alleged to have committed the offense.

(4) A description of the offense charged and the section of the code allegedly violated.

(c) Complaints must be submitted without unnecessary delay by a law enforcement officer to the prosecutor and, if he or she approves, to a judge to determine whether an arrest warrant or summons should be issued.

(d) When an accused has been arrested without a warrant, a complaint shall be filed forthwith with the court for review as to whether probable cause exists to hold the accused, and in no instance shall a complaint be filed later than at the time of arraignment.

§ 11.301 Arrests.

(a) Arrest is the taking of a person into police custody in order that he or she may be held to answer for a criminal offense.

(b) No law enforcement officer shall arrest any person for a criminal offense except when:

(1) The officer shall have a warrant signed by a magistrate commanding the arrest of such person, or the officer knows for a certainty that such a warrant has been issued; or

(2) The offense shall occur in the presence of the arresting officer; or

(3) The officer shall have probable cause to believe that the person arrested has committed an offense.

§ 11.302 Arrest warrants.

(a) Each magistrate of a Court of Indian Offenses shall have the authority to issue warrants to apprehend any person the magistrate has probable cause to believe has committed a criminal offense in violation of the regulations under this part based on a written complaint filed with the court by a law enforcement officer and bearing the signature of the complainant.

(b) The arrest warrant shall contain the following information:

(1) Name or description and address, if known, of the person to be arrested.

(2) Date of issuance of the warrant.

(3) Description of the offense charged.

(4) Signature of the issuing magistrate.

(c) Such warrants may be served only by a BIA or tribal police officer or other officer commissioned to enforce the regulations of this part.

§ 11.303 Notification of rights prior to custodial interrogation.

Prior to custodial interrogation, the suspect shall be advised of the following rights:

(a) That he or she has the right to remain silent.

(b) That any statements made by him or her may be used against him or her in court.

(c) That he or she has the right to obtain counsel and, if indigent, to have counsel appointed for him/her.

§ 11.304 Summons in lieu of warrant.

(a) When otherwise authorized to arrest a suspect, a law enforcement officer or a magistrate may, in lieu of a warrant, issue a summons commanding the accused to appear before the Court of Indian Offenses at a stated time and place and answer to the charge.

(b) The summons shall contain the same information as a warrant, except that it may be signed by a police officer.

(c) The summons shall state that if a defendant fails to appear in response to a summons, a warrant for his or her arrest shall be issued.

(d) The summons, together with a copy of the complaint, shall be served upon the defendant by delivering a copy to the defendant personally or by leaving a copy at his or her usual residence or place of business with any person 18 years of age or older who also resides or works there. Service shall be made by an authorized law enforcement officer, who shall file with the record of the case a form indicating when the summons was served.

§ 11.305 Search warrants.

(a) Each magistrate of a Court of Indian Offenses shall have the authority to issue a warrant for the search of premises and for the seizure of physical evidence of a criminal violation under the regulations of this part located within the Indian country over which the court has jurisdiction.

(b) No warrant for search or seizure may be issued unless it is based on a written and signed statement establishing, to the satisfaction of the magistrate, that probable cause exists to believe that the search will lead to discovery of evidence of a criminal violation under the regulations of this part.

(c) No warrant for search or seizure shall be valid unless it contains the name or description of the person, vehicle, or premises to be searched, describes the evidence to be seized, and bears the signature of the magistrate who issued it.

(d) Warrants may be executed only by a BIA or tribal police officer or other official commissioned to enforce the regulations under this part. The executing officer shall return the warrant to the Court of Indian Offenses within the time limit shown on the face of the warrant, which in no case shall be longer than ten (10) days from the date of issuance. Warrants not returned within such time limits shall be void.

§ 11.306 Search without a warrant.

No law enforcement officer shall conduct any search without a valid warrant except:

(a) Incident to making a lawful arrest; or

(b) With the voluntary consent of the person being searched; or

(c) When the search is of a moving vehicle and the officer has probable cause to believe that it contains contraband, stolen property, or property otherwise unlawfully possessed.

§ 11.307 Disposition of seized property.

(a) The officer serving and executing a warrant shall make an inventory of all seized property, and a copy of such inventory shall be left with every person from whom property is seized.

(b) A hearing shall be held by the Court of Indian Offenses to determine the disposition of all seized property. Upon satisfactory proof of ownership, the property shall be delivered immediately to the owner, unless such property is contraband or is to be used as evidence in a pending case. Property seized as evidence shall be returned to the owner after final judgment. Property confiscated as contraband shall be destroyed or otherwise lawfully disposed of as ordered by the Court of Indian Offenses.

§ 11.308 Commitments.

No person may be detained, jailed or imprisoned under the regulations of this part for longer than 48 hours unless the Court of Indian Offenses issues a commitment bearing the signature of a magistrate. A temporary commitment shall be issued for each person held before trial. A final commitment shall be issued for each person sentenced to jail after trial.

§ 11.309 Arraignments.

(a) Arraignment is the bringing of an accused before the court, informing him or her of his or her rights and of the charge(s) against him or her, receiving the plea, and setting conditions of pretrial release as appropriate in accordance with this part.

(b) Arraignment shall be held in open court without unnecessary delay after the accused is taken into custody and in no instance shall arraignment be later than the next regular session of court.

(c) Before an accused is required to plead to any criminal charges the magistrate shall:

(1) Read the complaint to the accused and determine that he or she understands it and the section(s) of this part that he or she is charged with violating, including the maximum authorized penalty; and

(2) Advise the accused that he or she has the right to remain silent, to be tried by a jury if the offense charged is punishable by imprisonment, to be represented by counsel (which shall be paid for by the government if the accused is indigent) and that the arraignment will be postponed should he or she desire to consult with counsel.

(d) The magistrate shall call upon the defendant to plead to the charge:

(1) If the accused pleads "not guilty" to the charge, the magistrate shall then inform the accused of the trial date and set conditions for release prior to trial.

(2) If the accused pleads "guilty" to the charge, the magistrate shall accept the plea only if he or she is satisfied that the plea is made voluntarily and that the accused understands the consequences of the plea, including the rights waived by the plea. The magistrate may then impose sentence or defer sentencing for a reasonable time in order to obtain any information he or she deems necessary for the imposition of a just sentence. The accused shall be afforded an opportunity to be heard by the court prior to sentencing.

(3) If the accused refuses to plead, the judge shall enter a plea of "not guilty" on his or her behalf.

(3) The court may, in its discretion, allow a defendant to withdraw a plea of guilty if it appears that the interest of justice would be served by doing so.

§ 11.310 Bail.

(a) Each person charged with a criminal offense under this part shall be entitled to release from custody pending trial under whichever one or more of the following conditions is deemed necessary to reasonably assure the appearance of the person at any time lawfully required:

(1) Release on personal recognizance upon execution by the accused of a written promise to appear at trial and all other lawfully required times;

(2) Release to the custody of a designated person or organization agreeing to assure the accused's appearance;

(3) Release with reasonable restrictions on the travel, association, or place of residence of the accused during the period of release;

(4) Release after deposit of a bond or other sufficient collateral in an amount specified by the magistrate or a bail schedule;

(5) Release after execution of a bail agreement by two responsible members of the community; or

(6) Release upon any other condition deemed reasonably necessary to assure the appearance of the accused as required.

(b) Any law enforcement officer authorized to do so by the court may admit an arrested person to bail pending trial pursuant to a bail schedule and conditions prepared by the court.

(c) A convicted person may be released from custody pending appeal on such conditions as the magistrate determines will reasonably assure the appearance of the accused unless the magistrate determines that release of the accused is likely to pose a danger to the community, the accused, or any other person.

(d) The Court of Indian Offenses may revoke its release of the defendant and order him or her committed at any time where it determines that the conditions of release will not reasonably assure the appearance of the defendant, or if any conditions of release have been violated.

§ 11.311 Subpoenas.

(a) Upon request of any party, the court shall issue subpoenas to compel the testimony of witnesses, or the production of books, records, documents or any other physical evidence relevant to the determination of the case and not an undue burden on the person possessing the evidence. The clerk of the court may act on behalf of the court and issue subpoenas which have been signed either by the clerk of the court or by a magistrate of the Court of Indian Offenses and which are to be served within Indian country over which the Court of Indian Offenses has jurisdiction.

(b) A subpoena shall bear the signature of the chief magistrate of the Court of Indian Offenses, and it shall state the name of the court, the name of the person or description of the physical evidence to be subpoenaed, the title of the proceeding, and the time and place where the witness is to appear or the evidence is to be produced.

(c) A subpoena may be served at any place but any subpoena to be served outside of the Indian country over which the Court of Indian Offenses has jurisdiction shall be issued personally by a magistrate of the Court of Indian Offenses.

(d) A subpoena may be served by any law enforcement officer or other person appointed by the court for such purpose. Service of a subpoena shall be made by delivering a copy of it to the person named or by leaving a copy at his or her place of residence or business with any person 18 years of age or older who also resides or works there.

(e) Proof of service of the subpoena shall be filed with the clerk of the court by noting on the back of the subpoena the date, time and place that it was served and noting the name of the person to whom it was delivered. Proof of service shall be signed by the person who actually served the subpoena.

(f) In the absence of a justification satisfactory to the court, a person who fails to obey a subpoena may be deemed to be in contempt of court and a bench

warrant may be issued for his or her arrest.

§ 11.312 Witness fees.

(a) Each fact witness answering a subpoena is entitled to a fee of not less than the hourly minimum wage scale established by 29 U.S.C. 206(a)(1) and any of its subsequent revisions, plus actual cost of travel. Each fact witness testifying at a hearing shall receive pay for a full day (eight hours) plus travel allowance.

(b) The Court of Indian Offenses may order any party calling a witness to testify without a subpoena to compensate the witness for actual traveling and living expenses incurred in testifying.

(c) If the Court of Indian Offenses finds that a complaint was not filed in good faith but with a frivolous or malicious intent, it may order the complainant to reimburse the court for expenditures incurred under this section, and such order may constitute a judgment upon which execution may levy.

§ 11.313 Trial procedure.

(a) The time and place of court sessions, and all other details of judicial procedure shall be set out in rules of court approved by the chief magistrate of the Court of Indian Offenses.

(b) Courts of Indian Offenses shall be bound by the Federal Rules of Evidence, except insofar as such rules are superseded by order of the court or by the existence of inconsistent tribal rules of evidence.

§ 11.314 Jury trials.

(a) In any criminal case punishable by a sentence of six months in jail and in any criminal case in which the prosecutor informs the court before the case comes to trial that a jail sentence will be sought, the defendant has a right, upon demand, to a jury trial. If the prosecutor informs the court that no prison sentence will be sought, the court may not impose a prison sentence for the offense.

(b) A jury shall consist of eight Indian residents of the vicinity in which trial is held, selected from a list of eligible jurors prepared each year by the court. An eligible juror shall be at least 18 years of age, shall not have been convicted of a felony, and shall not otherwise be unqualified according to standards established by the Court of Indian Offenses under its general rulemaking authority. Any party may challenge without cause not more than three members of the jury panel so chosen.

(c) The magistrate shall instruct the jury with regard to the applicable law and the jury shall decide all questions of fact on the basis of the law.

(d) The jury shall deliberate in secret and return a verdict of guilty or not guilty. Six out of the eight jurors must concur to render a verdict.

(e) Each juror who serves on a jury is entitled to a fee not less than the hourly minimum wage scale established by 29 U.S.C. 206(a)(1), and any of its subsequent revisions, plus mileage not to exceed the maximum rate per mile established by the Federal Government of jurors and witnesses. Each juror shall receive pay for a full day (eight hours) for any portion of a day served, plus travel allowance.

§ 11.315 Sentencing.

(a) Any person who has been convicted in a Court of Indian Offenses of a criminal offense under the regulations of this part may be sentenced to one or a combination of the following penalties:

(1) Imprisonment for a period not to exceed the maximum permitted by the section defining the offense, which in no case shall be greater than six months.

(2) A money fine in an amount not to exceed the maximum permitted by the section defining the offense, which in no case shall be greater than five hundred dollars ($500).

(3) Labor for the benefit of the tribe.

(4) Rehabilitative measures.

(b) In addition to or in lieu of the penalties provided in paragraph (a) of this section, the court may require a convicted offender who has inflicted injury upon the person or property of another to make restitution or compensate the injured person by means of the surrender of property, payment of money damages, or the performance of any other act for the benefit of the injured party.

(c) If, solely because of indigence, a convicted offender is unable to pay forthwith a money fine assessed under any applicable section, the court shall allow him or her a reasonable period of time to pay the entire sum or allow him or her to make reasonable installment payments to the clerk of the court at specified intervals until the entire sum is paid. If the offender defaults on such payments the court may find him or her in contempt of court and imprison him or her accordingly.

§ 11.316 Probation.

(a) Where a sentence of imprisonment has been imposed on a convicted offender, the Court of Indian Offenses may, in its discretion, suspend the serving of such sentence and release the person on probation under any reasonable conditions deemed appropriate by the court, provided that the period of probation shall not exceed one year.

(b) Any person who violates the terms of his or her probation may be required by the court to serve the sentence originally imposed or such part of it as the court may determine to be suitable giving consideration to all the circumstances, provided that such revocation of probation shall not be ordered without a hearing before the court at which the offender shall have the opportunity to explain his or her actions.

§ 11.317 Parole.

(a) Any person sentenced by the court of detention or labor shall be eligible for parole at such time and under such reasonable conditions as set by the Court of Indian Offenses.

(b) Any person who violates the conditions of his or her parole may be required by the court to serve the whole original sentence, provided that such revocation or parole shall not be ordered without a hearing before the court at which the offender shall have the opportunity to explain his or her actions.

§ 11.318 Extradition.

Any Court of Indian Offenses may order delivery to the proper state, tribal or BIA law enforcement authorities of any person found within the jurisdiction of the court, who is charged with an offense in another jurisdiction. Prior to delivery to the proper officials, the accused shall be accorded a right to contest the propriety of the court's order in a hearing before the court.

Subpart D—Criminal Offenses

§ 11.400 Assault.

(a) A person is guilty of assault if he or she:

(1) Attempts to cause or purposely, knowingly or recklessly causes bodily injury to another; or

(2) Negligently causes bodily injury to another with a deadly weapon; or

(3) Attempts by physical menace to put another in fear of imminent serious bodily injury.

(b) Assault is a misdemeanor unless committed in a fight or scuffle entered into by mutual consent, in which case it is a petty misdemeanor.

§ 11.401 Recklessly endangering another person.

A person commits a misdemeanor if he or she recklessly engages in conduct which places or may place another person in danger of death or serious bodily injury. Recklessness and danger shall be presumed where a person

knowingly points a fireman at or in the direction of another person, whether or not the actor believed the firearm to be loaded.

§ 11.402 Terroristic threats.

A person is guilty of a misdemeanor if he or she threatens to commit any crime of violence with purpose to terrorize another or to cause evacuation of a building, place of assembly or facility of public transportation, or otherwise to cause serious public inconvenience or in reckless disregard of the risk of causing such terror or inconvenience.

§ 11.403 Unlawful restraint.

A person commits a misdemeanor if he or she knowingly:

(a) Restrains another unlawfully in circumstances exposing him or her to risk of serious bodily injury; or

(b) Holds another in a condition of involuntary servitude.

§ 11.404 False imprisonment.

A person commits a misdemeanor if he or she knowingly restrains another unlawfully so as to interfere substantially with his or her liberty.

§ 11.405 Interference with custody.

(a) *Custody of children.* A person commits a misdemeanor if he or she knowingly or recklessly takes or entices any child under the age of 18 from the custody of his or her parent, guardian or other lawful custodian, when he or she has no privilege to do so.

(b) *Custody of committed person.* A person is guilty of a misdemeanor if he or she knowingly or recklessly takes or entices any committed person away from lawful custody when he or she does not have the privilege to do so. *Committed person* means, in addition to anyone committed under judicial warrant, any orphan, neglected or delinquent child, mentally defective or insane person, or other dependent or incompetent person entrusted to another's custody by or through a recognized social agency or otherwise by authority of law.

§ 11.406 Criminal coercion.

(a) A person is guilty of criminal coercion if, with purpose to unlawfully restrict another's feedom of action to his or her detriment, he or she threatens to:

(1) Commit any criminal offense; or

(2) Accuse anyone of a criminal offense; or

(3) Take or withhold action as an official, or cause an official to take or withhold action.

(b) Criminal coercion is classified as a misdemeanor.

§ 11.407 Sexual assault.

(a) A person who has sexual contact with another person not his or her spouse, or causes such other person to have sexual contact with him or her, is guilty of sexual assualt as a misdemeanor, if:

(1) He or she knows that the conduct is offensive to the other person; or

(2) He or she knows that the other person suffers from a mental disease or defect which renders him or her incapable of appraising the nature or his or her conduct; or

(3) He or she knows that the other person is unaware that a sexual act is being committed; or

(4) The other person is less than ten years old; or

(5) He or she has substantially impaired the other person's power to appraise or control his or her conduct, by administering or employing without the other's knowledge drugs, intoxicants or other means for the purpose of preventing resistance; or

(6) The other person is less than 16 years old and the actor is at least four years older than the other person; or

(7) The other person is less than 21 years old and the actor is his or her guardian or otherwise responsible for general supervision of his or her welfare; or

(8) The other person is in custody of law or detained in a hospital or other institution and the actor has supervisory or disciplinary authority over him or her.

(b) Sexual contact is any touching of the sexual or other intimate parts of the person for the purpose of arousing or gratifying sexual desire, or for the purpose of abusing, humiliating, harassing, or degrading the victim.

§ 11.408 Indecent exposure.

A person commits a misdemeanor if he or she exposes his or her genitals under circumstances in which he or she knows his or her conduct is likely to cause affront or alarm.

§ 11.409 Reckless burning or exploding.

A person commits a misdemeanor if he or she purposely starts a fire or causes an explosion, whether on his or her property or another's, and thereby recklessly:

(a) Places another person in danger of death or bodily injury; or

(b) Places a building or occupied structure of another in danger of damage or destruction.

§ 11.410 Criminal mischief.

(a) A person is guilty of criminal mischief if he or she:

(1) Damages tangible property of another purposely, recklessly, or by negligence in the employment of fire, explosives, or other dangerous means; or

(2) Purposely or recklessly tampers with tangible property of another so as to endanger person or property; or

(3) Purposely or recklessly causes another to suffer pecuniary loss by deception or threat.

(b) Criminal mischief is a misdemeanor if the actor purposely causes pecuniary loss in excess of $100, or a petty misdemeanor if he or she purposely or recklessly causes precuniary loss in excess of $25. Otherwise, criminal mischief is a violation.

§ 11.411 Criminal trespass.

(a) A person commits an offense if, knowing that he or she is not licensed or privileged to do so, he or she enters or surreptitiously remains in any building or occupied structure. An offense under this subsection is a misdemeanor if it is committed in a dwelling at night. Otherwise it is a petty misdemeanor.

(b) A person commits an offense if, knowing that he or she is not licensed or privileged to do so, he or she enters or remains in any place as to which notice against trespass is given by:

(1) Actual communication to the actor; or

(2) Posting in a manner prescribed by law or reasonably likely to come to the attention of intruders; or

(3) Fencing or other enclosure manifestly designed to exclude intruders.

(c) An offense under this section constitutes a petty misdemeanor if the offender defies an order to leave personally communicated to him or her by the owner of the premises or other authorized person. Otherwise it is a violation.

§ 11.412 Theft.

A person who, without permission of the owner, shall take, shoplift, possess or exercise unlawful control over movable property not his or her own or under his or her control with the purpose to deprive the owner thereof or who unlawfully transfers immovable property of another or any interest therein with the purpose to benefit himself or herself or another not entitled thereto shall be guilty of theft, a misdemeanor.

§ 11.413 Receiving stolen property.

A person is guilty of receiving stolen property, a misdemeanor, if he or she purposely receives, retains, or disposes of movable property of another knowing that it has been stolen, or believing that

it has probably been stolen, unless the property is received, retained, or disposed with purpose to restore it to the owner. *Receiving* means acquiring possession, control or title, or lending on the security of the property.

§ 11.414 Embezzlement.

A person who shall, having lawful custody of property not his or her own, appropriate the same to his or her own use, with intent to deprive the owner thereof, shall be guilty of embezzlement, a misdemeanor.

§ 11.415 Fraud.

A person who shall by willful misrepresentation or deceit, or by false interpreting, or by the use of false weights or measures obtain any money or other property, shall be guilty of fraud, a misdemeanor.

§ 11.416 Forgery.

(a) A person is guilty of forgery, a misdemeanor, if, with purpose to defraud or injure anyone, or with knowledge that he or she is facilitating fraud or injury to be perpetrated by anyone, he or she:

(1) Alters, makes, completes, authenticates, issues or transfers any writing of another without his or her authority; or

(2) Utters any writing which he or she knows to be forged in a manner above specified.

(b) "Writing" includes printing or any other method of recording information, money, coins, tokens, stamps, seals, credit cards, badges, trademarks, and other symbols of value, right, privilege, or identification.

§ 11.417 Extortion.

A person who shall willfully, by making false charges against another person or by any other means whatsoever, extort or attempt to extort any moneys, goods, property, or anything else of any value, shall be guilty of extortion, a misdemeanor.

§ 11.418 Misbranding.

A person who shall knowingly and willfully misbrand or alter any brand or mark on any livestock of another person, shall be guilty of a misdemeanor.

§ 11.419 Unauthorized use of automobiles and other vehicles.

A person commits a misdemeanor if he or she operates another person's automobile, airplane, motorcycle, motorboat, or other motor-propelled vehicle without consent of the owner. It is an affirmative defense to prosecution under this section that the actor reasonably believed that the owner would have consented to the operation had he or she known of it.

§ 11.420 Tampering with records.

A person commits a misdemeanor if, knowing that he or she has no privilege to do so, he or she falsifies, destroys, removes or conceals any writing or record, with purpose to deceive or injure anyone or to conceal any wrongdoing.

§ 11.421 Bad checks.

(a) A person who issues or passes a check or similar sight order for the payment of money, knowing that it will not be honored by the drawee, commits a misdemeanor.

(b) For the purposes of this section, an issuer is presumed to know that the check or order would not be paid, if:

(1) The issuer had no account with the drawee at the time the check or order was issued; or

(2) Payment was refused by the drawee for lack of funds, upon presentation within 30 days after issue, and the issuer failed to make good within 10 days after receiving notice of that refusal.

§ 11.422 Unauthorized use of credit cards.

(a) A person commits a misdemeanor if he or she uses a credit card for the purpose of obtaining property or services with knowledge that:

(1) The card is stolen or forged; or

(2) The card has been revoked or cancelled; or

(3) For any other reason his or her use of the card is unauthorized by the issuer.

(b) *Credit card* means a writing or other evidence of an undertaking to pay for property or services delivered or rendered to or upon the order of a designated person or bearer.

§ 11.423 Defrauding secured creditors.

A person commits a misdemeanor if he or she destroys, conceals, encumbers, transfers or otherwise deals with property subject to a security interest with purpose to hinder that interest.

§ 11.424 Neglect of children.

(a) A parent, guardian, or other person supervising the welfare of a child under 18 commits a misdemeanor if he or she knowingly endangers the child's welfare by violating a duty of care, protection or support.

(b) A parent, guardian, or other person supervising the welfare of a child under 18 commits a violation if he or she neglects or refuses to send the child to school.

§ 11.425 Persistent non-support.

A person commits a misdemeanor if he or she persistently fails to provide support which he or she can provide and which he or she knows he or she is legally obliged to provide to a spouse, child or other dependent.

§ 11.426 Bribery.

(a) A person is guilty of bribery, a misdemeanor, if he or she offers, confers or agrees to confer upon another, or solicits, accepts or agrees to accept from another:

(1) Any pecuniary benefit as consideration for the recipient's decision, opinion, recommendation, vote or other exercise of discretion as a public servant, party official or voter; or

(2) Any benefit as consideration for the recipient's decision, vote, recommendation or other exercise of official discretion in a judicial or administrative proceeding; or

(3) Any benefit as consideration for a violation of a known legal duty as a public servant or party official.

(b) It is no defense to prosecution under this section that a person whom the actor sought to influence was not qualified to act in the desired way, whether because he or she had not yet assumed office, or lacked jurisdiction, or for any other reason.

§ 11.427 Threats and other improper influence in official and political matters.

(a) A person commits a misdemeanor if he or she:

(1) Threatens unlawful harm to any person with purpose to influence his or her decision, vote or other exercise of discretion as a public servant, party official or voter; or

(2) Threatens harm to any public servant with purpose to influence his decision, opinion, recommendation, vote or other exercise of discretion in a judicial or administrative proceeding; or

(3) Threatens harm to any public servant with purpose to influence his decision, opinion, recommendation, vote or other exercise of discretion in a judicial or administrative proceeding; or

(b) It is no defense to prosecution under this section that a person whom the actor sought to influence was not qualified to act in the desired way, whether because he or she had not yet assumed office, or lacked jurisdiction, or for any other reason.

§ 11.428 Retaliation for past official action.

A person commits a misdemeanor if he or she harms another by any unlawful act in retaliation for anything lawfully done by the latter in the capacity of public servant.

§ 11.429 Perjury.

A person is guilty of perjury, a misdemeanor, if in any official proceeding he or she makes a false

statement under oath or equivalent affirmation, or swears or affirms the truth of a statement previously made, when the statement is material and he or she does not believe it to be true.

(a) No person shall be guilty of an offense under this section if he or she retracted the falsification in the course of the proceeding in which it was made before it became manifest that the falsification was or would be exposed and before the falsification substantially affected the proceeding.

(b) No person shall be convicted of an offense under this section where proof of falsity rests solely upon contradiction by testimony of a single person other than the defendant.

§ 11.430 False alarms.

A person who knowingly causes a false alarm of fire or other emergency to be transmitted to, or within any organization, official or volunteer, for dealing with emergencies involving danger to life or property commits a misdemeanor.

§ 11.431 False reports.

(a) A person who knowingly gives false information to any law enforcement officer with the purpose to implicate another commits a misdemeanor.

(b) A person commits a petty misdemeanor if he or she:

(1) Reports to law enforcement authorities an offense or other incident within their concern knowing that it did not occur; or

(2) Pretends to furnish such authorities with information relating to an offense or incident when he or she knows he or she has no information relating to such offense or incident.

§ 11.432 Impersonating a public servant.

A person commits a misdemeanor if he or she falsely pretends to hold a position in the public service with purpose to induce another to submit to such pretended official authority or otherwise to act in reliance upon that pretense to his or her prejudice.

§ 11.433 Disobedience to lawful order of court.

A person who willfully disobeys any order, subpoena, summons, warrant or command duly issued, made or given by any Court of Indian Offenses or any officer thereof is guilty of a misdemeanor.

§ 11.434 Resisting arrest.

A person commits a misdemeanor if, for the purpose of preventing a public servant from effecting a lawful arrest or discharging any other duty, he or she creates a substantial risk of bodily injury to the public servant or anyone else, or employs means justifying or requiring substantial force to overcome the resistance.

§ 11.435 Obstructing justice.

A person commits a misdemeanor if, with purpose to hinder the apprehension, prosecution, conviction or punishment of another for a crime, he or she harbors or conceals the other, provides a weapon, transportation, disguise or other means of escape, warns the other of impending discovery, or volunteers false information to a law enforcement officer.

§ 11.436 Escape.

A person is guilty of the offense of escape, a misdemeanor, if he or she unlawfully removes himself or herself from official detention or fails to return to official detention following temporary leave granted for a specific purpose or limited period.

§ 11.437 Bail jumping.

A person set at liberty by court order, with or without bail, upon condition that he or she will subsequently appear at a specified time or place, commits a misdemeanor if, without lawful excuse, he or she fails to appear at that time and place.

§ 11.438 Flight to avoid prosecution or judicial process.

A person who shall absent himself or herself from the Indian country over which the Court of Indian Offenses exercises jurisdiction for the purpose of avoiding arrest, prosecution or other judicial process shall be guilty of a misdemeanor.

§ 11.439 Witness tampering.

(a) A person commits a misdemeanor if, believing that an official proceeding or investigation is pending or about to be instituted, he or she attempts to induce or otherwise cause a witness or informant to:

(1) Testify or inform falsely; or

(2) Withhold any testimony, information, document or thing; or

(3) Elude legal process summoning him or her to supply evidence; or

(4) Absent himself or herself from any proceeding or investigation to which he or she has been legally summoned.

(b) A person commits a misdemeanor if he or she harms another by any unlawful act in retaliation for anything lawfully done in the capacity of witness or informant.

§ 11.440 Tampering with or fabricating physical evidence.

A person commits a misdemeanor if, believing that an official proceeding or investigation is pending or about to be instituted, he or she:

(a) Alters, destroys, conceals, or removes any record, document or thing with purpose to impair its verity or availability in such proceeding or investigation; or

(b) Makes, presents or uses any record, document or thing knowing it to be false and with the purpose to mislead a public servant who is or may be engaged in such proceeding or investigation.

§ 11.441 Disorderly conduct.

(a) A person is guilty of disorderly conduct if, with purpose to cause public inconvenience, annoyance or alarm or recklessly creating a risk thereof, he or she:

(1) Engages in fighting or threatening, or in violent or tumultuous behavior;

(2) Makes unreasonable noise or offensively coarse utterance, gesture or display, or addresses abusive language to any person present; or

(3) Creates a hazardous or physically offensive condition by any act which serves no legitimate purpose of the actor.

(b) *Public* means affecting or likely to affect persons in a place to which the public has access; among the places included are highways, schools, prisons, apartments, places of business or amusement, or any neighborhood.

(c) An offense under this section is a petty misdemeanor if the actor's purpose is to cause substantial harm or serious inconvenience, or if he or she persists in disorderly conduct after reasonable warning or request to desist. Otherwise, disorderly conduct is a violation.

§ 11.442 Riot; failure to disperse.

(a) A person is guilty of riot, a misdemeanor, if he or she participates with two or more others in a course of disorderly conduct:

(1) With purpose to commit or facilitate the commission of a felony or misdemeanor; or

(2) With purpose to prevent or coerce official action; or

(3) When the actor or any other participant to the knowledge of the actor uses or plans to use a firearm or other deadly weapon.

(b) Where three or more persons are participating in a course of disorderly conduct likely to cause substantial harm or serious inconvenience, a law enforcement officer may order the participants and others in the immediate vicinity to disperse. A person who refuses or knowingly fails to obey such an order commits a misdemeanor.

§ 11.443 Harassment.

A person commits a petty misdemeanor if, with purpose to harass another, he or she:

(a) Makes a telephone call without purpose or legitimate communication; or

(b) Insults, taunts or challenges another in a manner likely to provoke violent or disorderly response; or

(c) Makes repeated communications anonymously or at extremely inconvenient hours, or in offensively coarse language; or

(d) Subjects another to an offensive touching; or

(e) Engages in any other course of alarming conduct serving no legitimate purpose.

§ 11.444 Carrying concealed weapons.

A person who goes about in public places armed with a dangerous weapon concealed upon his or her person is guilty of a misdemeanor unless he or she has a permit to do so signed by a magistrate of the Court of Indian Offenses.

§ 11.445 Driving violations.

(a) A person who shall operate any vehicle in a manner dangerous to the public safety is guilty of reckless driving, a petty misdemeanor, unless it is committed while under the influence of alcohol, in which case it is a misdemeanor.

(b) A person who shall drive, operate or be in physical control of any motor vehicle when his or her alcohol concentration is 0.10 or more shall be guilty of driving while intoxicated, a misdemeanor.

(c) Any person who drives, operates, or is in physical control of a motor vehicle within the Indian country under the jurisdiction of a Court of Indian Offenses consents to a chemical test of his or her blood, breath, or urine for the purpose of determining the presence of alcohol, to be administered at the direction of a law enforcement officer. The test may be required when the officer has reasonable cause to believe that a person is driving while intoxicated, and the person has either been lawfully placed under arrest for a violation of this section, or has been involved in a motor vehicle accident or collision resulting in property damage, personal injury, or death.

(d) In the absence of an applicable tribal traffic code, the provisions of state traffic laws applicable in the state where a Court of Indian Offenses is located shall apply to the operation of motor vehicles within the Indian country under the jurisdiction of the Court of Indian Offenses with the exception that any person found guilty of violating such laws shall, in lieu of the penalties provided under state law, be sentenced according to the standards found in § 11.450 depending on the nature of the traffic code violation, and may be deprived of the right to operate any motor vehicle for a period not to exceed 6 months.

§ 11.446 Cruelty to animals.

A person commits a misdemeanor if he or she purposely or recklessly:

(a) Subjects any animal in his or her custody to cruel neglect; or

(b) Subjects any animal to cruel mistreatment; or

(c) Kills or injures any animal belonging to another without legal privilege or consent of the owner.

(d) Causes one animal to fight with another.

§ 11.447 Maintaining a public nuisance.

A person who permits his or her property to fall into such condition as to injure or endanger the safety, health, comfort, or property of his or her neighbors, is guilty of a violation.

§ 11.448 Abuse of office.

A person acting or purporting to act in an official capacity or taking advantage of such actual or purported capacity commits a misdemeanor if, knowing that his or her conduct is illegal, he or she:

(a) Subjects another to arrest, detention, search, seizure, mistreatment, dispossession, assessment, lien or other infringement of personal or property rights; or

(b) Denies or impedes another in the exercise or enjoyment of any right, privilege, power or immunity.

§ 11.449 Violation of an approved tribal ordinance.

A person who violates the terms of any tribal ordinance duly enacted by the governing body of the tribe occupying the Indian country under the jurisdiction of the Court of Indian Offenses and approved by the Assistant Secretary—Indian Affairs or his or her designee, is guilty of an offense and upon conviction thereof shall be sentenced as provided in the ordinance.

§ 11.450 Maximum fines and sentences of imprisonment.

(a) A person convicted of an offense under this code may be sentenced as follows:

(1) If the offense is a misdemeanor, to a term of imprisonment not to exceed six months or to a fine not to exceed $500.00, or both;

(2) If the offense is a petty misdemeanor, to a term of imprisonment not to exceed three months or to a fine not to exceed $250.00, or both;

(3) If the offense is a violation, to a term of imprisonment not to exceed one month or to a fine not to exceed $100.00, or both;

(b) The fines listed above may be imposed in addition to any amounts ordered paid as restitution.

Subpart E—Civil Actions

§ 11.500 Law applicable to civil actions.

(a) In all civil cases the Court of Indian Offenses shall apply any laws of the United States that may be applicable, any authorized regulations of the Interior Department, and any ordinances or customs of the tribe occupying the area of Indian country over which the court has jurisdiction, not prohibited by Federal laws.

(b) Where any doubt arises as to the customs and usages of the tribe the court may request the advice of counselors familiar with these customs and usages.

(c) Any matters that are not covered by the traditional customs and usages of the tribe, or by applicable Federal laws and regulations, shall be decided by the Court of Indian Offenses according to the law of the State in which the matter in dispute lies.

§ 11.501 Judgments in civil actions.

(a) In all civil cases, judgment shall consist of an order of the court awarding damages to be paid to the injured party, or directing the surrender of certain property to the injured party, or the performance of some other act for the benefit of the injured party, including injunctive relief and declaratory judgments.

(b) Where the injury inflicted was the result of carelessness of the defendant, the judgment shall fairly compensate the injured party for the loss he or she has suffered.

(c) Where the injury was deliberately inflicted, the judgment shall impose an additional penalty upon the defendant, which additional penalty may run either in favor of the injured party or in favor of the tribe.

(d) Where the injury was inflicted as a result of accident, or where both the complainant and the defendant were at fault, the judgment shall compensate the injured party for a reasonable part of the loss he or she has suffered.

(e) No judgment shall be given on any suit unless the defendant has actually received notice of such suit and ample opportunity to appear in court in his or her defense.

§ 11.502 Costs in civil actions.

(a) The court may assess the accruing costs of the case against the party or parties against whom judgment is given. Such costs shall consist of the expenses of voluntary witnesses for which either party may be responsible and the fees of jurors in those cases where a jury trial is had, and any further incidental expenses connected with the procedure before the court as the court may direct.

(b) In all civil suits the complainant may be required to deposit with the clerk of the court a fee or other security in a reasonable amount to cover costs and disbursements in the case.

§ 11.503 Applicable civil procedure.

The procedure to be followed in civil cases shall be the Federal Rules of Civil Procedure applicable to United States district courts, except insofar as such procedures are superseded by order of the Court of Indian Offenses or by the existence of inconsistent tribal rules of procedure.

§ 11.504 Applicable rules of evidence.

Courts of Indian Offenses shall be bound by the Federal Rules of Evidence, except insofar as such rules are superseded by order of the Court of Indian Offenses, or by the existence of inconsistent tribal rules of evidence.

Supart F—Domestic Relations

§ 11.600 Marriages.

(a) A magistrate of the Court of Indian Offenses shall have the authority to perform marriages.

(b) A valid marriage shall be constituted by:

(1) The issuance of a marriage license by the Court of Indian Offenses and by execution of a consent to marriage by both parties to the marriage and recorded with the clerk of the court; or

(2) The recording of a tribal custom marriage with the Court of Indian Offenses within 30 days of the tribal custom marriage ceremony by the signing by both parties of a marriage register maintained by the clerk of the court.

(c) A marriage license application shall include the following information:

(1) Name, sex, occupation, address, social security number, and date and place of birth of each party to the proposed marriage;

(2) If either party was previously married, his or her name, and the date, place, and court in which the marriage was dissolved or declared invalid or the date and place of death of the former spouse;

(3) Name and address of the parents or guardian of each party;

(4) Whether the parties are related to each other and, if so, their relationship; and

(5) The name and date of birth of any child of which both parties are parents, born before the making of the application, unless their parental rights and the parent and child relationship with respect to the child have been terminated.

(6) A certificate of the results of any medical examination required by either applicable tribal ordinances, or the laws of the State in which the Indian country under the jurisdiction of the Court of Indian Offenses is located.

§ 11.601 Marriage licenses.

A marriage license shall be issued by the clerk of the court in the absence of any showing that the proposed marriage would be invalid under any provision of this part or tribal custom, and upon written application of an unmarried male and unmarried female, both of whom must be eighteen (18) years or older. If either party to the marriage is under the age of eighteen (18), that party must have the written consent of parent or his or her legal guardian.

§ 11.602 Solemnization.

(a) In the event a judge, clergyman, tribal official or anyone authorized to do so solemnizes a marriage, he or she shall file with the clerk of the court certification thereof within thirty (30) days of the solemnization.

(b) Upon receipt of the marriage certificate, the clerk of the court shall register the marriage.

§ 11.603 Invalid or prohibited marriages.

(a) The following marriages are prohibited:

(1) A marriage entered into prior to the dissolution of an earlier marriage of one of the parties;

(2) A marriage between an ancestor and a descendant, or between a brother and a sister, whether the relationship is by the half or the whole blood;

(3) A marriage between an aunt and a nephew or between an uncle and a niece, whether the relationship is by the half or the whole blood, except as to marriages permitted by established tribal custom;

(4) A marriage prohibited by custom and usage of the tribe.

(b) Children born of a prohibited marriage are legitimate.

§ 11.604 Declaration of invalidity.

(a) The Court of Indian Offenses shall enter a decree declaring the invalidity of a marriage entered into under the following circumstances:

(1) A party lacked capacity to consent to the marriage, either because of mental incapacity or infirmity or by the influence of alcohol, drugs, or other incapacitating substances; or

(2) A party was induced to enter into a marriage by fraud or duress; or

(3) A party lacks the physical capacity to consummate the marriage by sexual intercourse and at the time the marriage was entered into, the other party did not know of the incapacity; or

(4) The marriage is prohibited under § 11.603.

(b) A declaration of invalidity may be sought by either party to the marriage or by the legal representative of the party who lacked capacity to consent.

§ 11.605 Dissolution.

(a) The Court of Indian Offenses shall enter a decree of dissolution of marriage if:

(1) The court finds that the marriage is irretrievably broken, if the finding is supported by evidence that (i) the parties have lived separate and apart for a period of more than 180 days next preceding the commencement of the proceeding, or (ii) there is serious marital discord adversely affecting the attitude of one or both of the parties towards the marriage;

(2) The court finds that either party, at the time the action was commenced, was domiciled within the Indian country under the jurisdiction of the court, and that the domicile has been maintained for 90 days next preceding the making of the findings; and

(3) To the extent it has jurisdiction to do so, the court has considered, approved, or provided for child custody, the support of any child entitled to support, the maintenance of either spouse, and the disposition of property; or has provided for a separate later hearing to complete these matters.

(b) If a party requests a decree of legal separation rather than a decree of dissolution of marriage, the Court of Indian Offenses shall grant the decree in that form unless the other party objects.

§ 11.606 Dissolution proceedings.

(a) Either or both parties to the marriage may initiate dissolution proceedings.

(b) If a proceeding is commenced by one of the parties, the other party shall be served in the manner provided by the applicable rule of civil procedure and within thirty days after the date of service may file a verified response.

(c) The verified petition in a proceeding for dissolution of marriage or legal separation shall allege that the marriage is irretrievably broken and shall set forth:

(1) The age, occupation, and length of residence within the Indian country

under the jurisdiction of the court of each party;

(2) The date of the marriage and the place at which it was registered;

(3) That jurisdictional requirements are met and that the marriage is irretrievably broken in that either (i) the parties have lived separate and apart for a period of more than 180 days next preceding the commencement of the proceeding or (ii) there is a serious marital discord adversely affecting the attitude of one or both of the parties toward the marriage, and there is no reasonable prospect of reconciliation;

(4) The names, age, and addresses of all living children of the marriage and whether the wife is pregnant;

(5) Any arrangement as to support, custody, and visitation of the children and maintenance of a spouse; and

(6) The relief sought.

§ 11.607 Temporary orders and temporary injunctions.

(a) In a proceeding for dissolution of marriage or for legal separation, either party may move for temporary maintenance or temporary support of a child of the marriage entitled to support. The motion shall be accompanied by an affidavit setting forth the factual basis for the motion and the amounts requested.

(b) As a part of a motion for temporary maintenance or support or by an independent motion accompanied by an affidavit, either party may request the Court of Indian Offenses to issue a temporary injunction for any of the following relief:

(1) Restraining any person from transferring, encumbering, concealing, or otherwise disposing of any property except in the usual course of business or for the necessities of life, and, if so restrained, requiring him or her to notify the moving party of any proposed extraordinary expenditures made after the order is issued;

(2) Enjoining a party from molesting or disturbing the peace of the other party or of any child;

(3) Excluding a party from the family home or from the home of the other party upon a showing that physical or emotional harm would otherwise result;

(4) Enjoining a party from removing a child from the jurisdiction of the court; and

(5) Providing other injunctive relief proper in the circumstances.

(c) The court may issue a temporary restraining order without requiring notice to the other party only if it finds on the basis of the moving affidavit or other evidence that irreparable injury will result to the moving party if no order is issued until the time for responding has elapsed.

(d) A response may be filed within 20 days after service of notice of a motion or at the time specified in the temporary restraining order.

(e) On the basis of the showing made, the Court of Indian Offenses may issue a temporary injunction and an order for temporary maintenance or support in amounts and on terms just and proper under the circumstances.

(f) A temporary order or temporary injunction:

(1) Does not prejudice the rights of the parties or the child which are to be adjudicated at subsequent hearings in a proceeding;

(2) May be revoked or modified before the final decree as deemed necessary by the court;

(3) Terminates when the final decree is entered or when the petition for dissolution or legal separation is voluntarily dismissed.

§ 11.608 Final decree; disposition of property; maintenance; child support; custody.

(a) A decree of dissolution of marriage or of legal separation is final when entered, subject to the right of appeal.

(b) The Court of Indian Offenses shall have the power to impose judgment as follows in dissolution or separation proceedings:

(1) Apportion or assign between the parties the non-trust property and non-trust assets belonging to either or both and whenever acquired, and whether the title thereto is in the name of the husband or wife or both;

(2) Grant a maintenance order for either spouse in amounts and for periods of time the court deems just;

(3) Order either or both parents owing a duty of support to a child to pay an amount reasonable or necessary for his or her support, without regard to marital misconduct, after considering all relevant factors. In addition:

(i) When a support order is issued by a Court of Indian Offenses, the order may provide that a portion of an absent parent's wages be withheld to comply with the order on the earliest of the following dates: When an amount equal to one month's support becomes overdue; when the absent parent requests withholding; or at such time as the Court of Indian Offenses selects. The amount to be withheld may include an amount to be applied toward liquidation of any overdue support.

(ii) If the Court of Indian Offenses finds that an absent parent who has been ordered to pay child support is now residing within the jurisdiction of another Court of Indian Offenses, an Indian tribal court, or a state court, it shall petition such court for reciprocal enforcement and provide it with a copy of the support order.

(iii) If the Court of Indian Offenses receives a petition from another Court of Indian Offenses, an Indian tribal court or a state court, it shall take necessary steps to determine paternity, establish an order for child support, register a foreign child support order or enforce orders as requested in the petition.

(iv) The Court of Indian Offenses shall assist a state in the enforcement and collection of past-due support from Federal tax refunds of absent parents living within the Indian country over which the court has jurisdiction.

(v) Any person or agency who has provided support or assistance to a child under 18 years of age shall be a proper person to bring an action under this section and to recover judgment in an amount equal to such past-paid support or assistance, including costs of bringing the action.

(4) Make child custody determinations in accordance with the best interest of the child.

(5) Restore the maiden name of the wife.

§ 11.609 Determination of paternity and support.

The Court of Indian Offenses shall have jurisdiction of all suits brought to determine the paternity of a child and to obtain a judgment for the support of the child. A judgment of the court establishing the identity of the father of the child shall be conclusive of that fact in all subsequent determinations of inheritance by the Court of Indian Offenses or by the Department of the Interior.

§ 11.610 Appointment of guardians.

The court shall have the jurisdiction to appoint or remove legal guardians for minors and for persons who are incapable of managing their own affairs under terms and conditions to be prescribed by the court.

§ 11.611 Change of name.

The Court of Indian Offenses shall have the authority to change the name of any person upon petition of such person or upon the petition of the parents of any minor, if at least one parent is Indian. Any order issued by the court for a change of name shall be kept as a permanent record and copies shall be filed with the agency superintendent, the governing body of the tribe occupying the Indian country under the jurisdiction of the court, and any appropriate agency of the State in which the court is located.

Subpart G—Probate Proceedings

§ 11.700 Probate jurisdiction.

The Court of Indian Offenses shall have jurisdiction to administer in probate the estate of a deceased Indian who, at the time of his or her death, was domiciled or owned real or personal property situated within the Indian country under the jurisdiction of the court to the extent that such estate consists of property which does not come within the jurisdiction of the Secretary of the Interior.

§ 11.701 Duty to present will for probate.

Any custodian of a will shall deliver the same to the Court of Indian Offenses within 30 days after receipt of information that the maker thereof is deceased. Any custodian who fails to do so shall be liable for damages sustained by any person injured thereby.

§ 11.702 Proving and admitting will.

(a) Upon initiating the probate of an estate, the will of the decedent shall be filed with the court. Such will may be proven and admitted to probate by filing an affidavit of an attesting witness which identifies such will as being the will which the decedent executed and declared to be his or her last will. If the evidence of none of the attesting witnesses is available, the court may allow proof of the will by testimony that the signature of the testator is genuine.

(b) At any time within 90 days after a will has been admitted to probate, any person having an interest in the decedent's estate may contest the validity of such will. In the event of such contest, a hearing shall be held to determine the validity of such will.

(c) Upon considering all relevant information concerning the will, the Court of Indian Offenses shall enter an order affirming the admission of such will to probate, or rejecting such will and ordering that the probate of the decedent's estate proceed as if the decedent had died intestate.

§ 11.703 Petition and order to probate estate.

(a) Any person having an interest in the administration of an estate which is subject to the jurisdiction of the court may file a written petition with the court requesting that such estate be administered in probate.

(b) The Court of Indian Offenses shall enter an order directing that the estate be probated upon finding that the decedent was an Indian who, at the time of his or her death, was domiciled or owned real or personal property situated within the Indian country under the jurisdiction of the court other than trust or other restricted property, that the decedent left an estate subject to the jurisdiction of the court, and that it is necessary to probate such estate.

§ 11.704 Appointment and duties of executor or administrator.

(a) Upon ordering the estate to be probated, the court shall appoint an administrator to administer the estate of the decedent. The person nominated by the decedent's will, if any, to be the executor of the estate shall be so appointed, provided such person is willing to serve in such capacity.

(b) The executor or administrator appointed by the court shall have the following duties and powers during the administration of the estate and until discharged by the court:

(1) To send by certified mail true copies of the order to probate the estate and the will of the decedent admitted to probate by such order, if any, to each heir, devisee and legatee of the decedent, at their last known address, to the governing body of the tribe or tribes occupying the Indian country over which the court has jurisdiction, and to the agency superintendent;

(2) To preserve and protect the decedent's property within the estate and the heirs, so far as is possible;

(3) To investigate promptly all claims against the decedent's estate and determine their validity;

(4) To cause a written inventory of all the decedent's property within the estate to be prepared promptly with each article or item being separately set forth and cause such property to be exhibited to and appraised by an appraiser, and the inventory and appraisal thereof to be filed with the court;

(5) To give promptly all persons entitled thereto such notice as is required under these proceedings;

(6) To account for all property within the estate which may come into his or her possession or control, and to maintain accurate records of all income received and disbursements made during the course of the administration.

§ 11.705 Removal of executor or administrator.

The Court of Indian Offenses may order the executor or administrator to show cause why he or she should not be discharged, and may discharge the executor or administrator for failure, neglect or improper performance of his or her duties.

§ 11.706 Appointment and duties of appraiser.

(a) Upon ordering an estate to be probated, the court shall appoint a disinterested and competent person as an appraiser to appraise all of the decedent's real and personal property within the estate.

(b) It shall be the duty of the appraiser to appraise separately the true cash value of each article or item of property within the estate, including debts due the decedent, and to indicate the appraised value of each such article or item of property set forth in the inventory of the estate and to certify such appraisal by subscribing his or her name to the inventory and appraisal.

§ 11.707 Claims against estate.

(a) Creditors of the estate or those having a claim against the decedent shall file their claim with the clerk of the court or with the executor or administrator within 60 days from official notice of the appointment of the executor or administrator published locally in the press or posting of signs at the tribal and agency offices, giving appropriate notice for the filing of claims.

(b) The executor or administrator shall examine all claims within 90 days of his or her appointment and notify the claimant whether his or her claim is accepted or rejected. If the claimant is notified of rejection, he or she may request a hearing before the court by filing a petition requesting such hearing within 30 days following the notice of rejection.

§ 11.708 Sale of property.

After filing the inventory and appraisal, the executor or administrator may petition the court for authority to sell personal property of the estate for purposes of paying the expenses of last illness and burial expenses, expenses of administration, claims, if any, against the estate, and for the purpose of distribution. If, in the court's judgment, such sale is in the best interest of the estate, the court shall order such sale and prescribe the terms upon which the property shall be sold.

§ 11.709 Final account.

(a) When the affairs of an estate have been fully administered, the executor or administrator shall file a final account with the court, verified by his or her oath. Such final account shall affirmatively set forth:

(1) That all claims against the estate have been paid, except as shown, and that the estate has adequate unexpended and unappropriated funds to fully pay such remaining claims;

(2) The amount of money received and expended by him or her, from whom received and to whom paid, referring to the vouchers for each of such payments;

(3) That there is nothing further to be done in the administration of the estate except as shown in the final account;

(4) The remaining assets of the estate, including unexpended and unappropriated money, at the time of filing the final account;

(5) The proposed determination of heirs and indicate the names, ages, addresses and relationship to the decedent of each distributee and the proposed distributive share and value thereof each heir, devisee or legatee is to receive; and

(6) A petition that the court set a date for conducting a hearing to approve the final account, to determine the heirs, devisees and legatees of the decedent and the distributive share each distributee is to receive.

§ 11.710 Determination of the court.

At the time set for hearing upon the final account, the Court of Indian Offenses shall proceed to examine all evidence relating to the distribution of the decedent's estate, and consider objections to the final account which may have been filed by any heir, devisee, legatee, or other person having an interest in the distribution of the estate. Upon conclusion of the hearing, the court shall enter an order:

(a) Providing for payment of approved claims;

(b) Determining the decedent's heirs, devisees and legatees, indicating the names, ages and addresses of each, and the distributive share of the remaining estate which each distributee is to receive; and

(c) Directing the administrator or executor to distribute such distributive share to those entitled thereto.

§ 11.711 Descent and distribution.

(a) The court shall distribute the estate according to the terms of the will of the decedent which has been admitted to probate.

(b) If the decedent died intestate or having left a will which has been rejected by the court, the estate shall be distributed as follows:

(1) According to the laws and customs of the tribe if such laws and customs are proved; or

(2) According to state law absent the existence of tribal laws or customs.

(c) If no person takes under the above subsections, the estate shall escheat to the tribe.

§ 11.712 Closing estate.

(a) Upon finding that the estate has been fully administered and is in a condition to be closed, the court shall enter an order closing the estate and discharging the executor or administrator.

(b) If an order closing the estate has not been entered by the end of nine months following appointment of executor or administrator, the executor or administrator shall file a written report with the court stating the reasons why the estate has not been closed.

§ 11.713 Small estates.

An estate having an appraised value which does not exceed $2,000.00 and which is to be inherited by a surviving spouse and/or minor children of the deceased may, upon petition of the executor or administrator, and a hearing before the court, be distributed without administration to those entitled thereto, upon which the estate shall be closed.

Subpart H—Appellate Proceedings

§ 11.800 Jurisdiction of appellate division.

The jurisdiction of the appellate division shall extend to all appeals from final orders and judgments of the trial division, by any party except the prosecution in a criminal case where there has been a jury verdict. The appellate division shall review all issues of law presented to it which arose in the case, but shall not reverse the trial division decision unless the legal error committed affected a substantial right of a party or the outcome of the case.

§ 11.801 Procedure on appeal.

(a) An appeal must be taken within 15 days from the judgment appealed from by filing a written notice of appeal with the clerk of the court.

(b) The notice of appeal shall specify the party or parties taking the appeal, shall designate the judgment, or part thereof appealed from, and shall contain a short statement of reasons for the appeal. The clerk of the court shall mail a copy of the notice of appeal to all parties other than parties taking the appeal.

(c) In civil cases, other parties shall have 15 days to respond to the notice of appeal.

(d) In civil cases, the appellant may request the trial division to stay the judgment pending action on the notice of appeal, and, if the appeal is allowed, either party may request the trial division to grant or stay an injunction pending appeal. The trial division may condition a stay or injunction pending appeal on the depositing of cash or bond sufficient to cover damages awarded by the court together with interest.

§ 11.802 Judgment against surety.

Any surety to a bond submits himself or herself to the jurisdiction of the Court of Indian Offenses, and irrevocably appoints the clerk of the court as his or her agent upon whom any papers affecting his or her liability on the bond may be served.

§ 11.803 Record on appeal.

Within 20 days after a notice of appeal is filed, the clerk of court shall certify and file with the appellate division the record of the case.

§ 11.804 Briefs and memoranda.

(a) Within 30 days after the notice of appeal is filed, the appellant may file a written brief in support of his or her appeal. An original and one copy for each appellee shall be filed with the clerk of court who shall mail one copy by registered or certified mail to each appellee.

(b) The appellee shall have 30 days after receipt of the appellant's brief within which to file an answer brief. An original and one copy for each appellant shall be filed with the clerk of the court who shall mail one copy, by registered or certified mail, to each appellant.

§ 11.805 Oral argument.

The appellate division shall assign all criminal cases for oral argument. The court may in its discretion assign civil cases for oral argument or may dispose of civil cases on the briefs without argument.

§ 11.806 Rules of court.

The chief magistrate of the appellate division shall prescribe all necessary rules concerning the operation of the appellate division and the time and place of meeting of the court.

Supart I—Children's Court

§ 11.900 Definitions.

For purposes of sections pertaining to the children's court:

(a) *Abandon* means the leaving of a minor without communication or failing to support a minor for a period of one year or more with no indication of the parents' willingness to assume a parental role.

(b) *Adult* means a person eighteen (18) years or older.

(c) *Counsel* means an attorney admitted to the bar of a state or the District of Columbia or a lay advocate admitted to practice before the Court of Indian Offenses.

(d) *Custodian* means one who has physical custody of a minor and who is providing food, shelter and supervision to the minor.

(e) *Custody* means the power to control the day-to-day activities of the minor.

(f) *Delinquent Act* means an act which, if committed by an adult, would be designated a crime under this part or under an ordinance of the tribe.

(g) *Detention* means the placement of a minor in a physically restrictive facility.

(h) *Guardian* means a person other than the minor's parent who is by law responsible for the care of the minor.

(i) *Guardian ad Litem* means a person appointed by the court to represent the minor's interests before the court.

(j) *Juvenile Offender* means a person who commits a delinquent act prior to his or her eighteenth birthday.

(k) *Minor* means:

(1) A person under 18 years of age,

(2) A person 18 years of age or older concerning whom proceedings are commenced in the children's court prior to his or her eighteenth birthday, or

(3) A person 18 years of age or older who is under the continuing jurisdiction of the children's court.

(l) *Minor-in-need-of-care* means a minor who:

(1) Has no parent or guardian available and willing to take care of him or her;

(2) Is unwilling to allow his or her parent or guardian to take care of him or her;

(3) Has suffered or is likely to suffer a physical or emotional injury, inflicted by other than accidental means, which causes or creates a substantial risk of death, disfigurement, impairment of bodily functions or emotional health;

(4) Has not been provided with adequate food, clothing, shelter, medical care, education or supervision by his or her parent, guardian or custodian;

(5) Has been sexually abused;

(6) Has been committing delinquent acts as a result of parental pressure, guidance or approval; or,

(7) Has been committing status offenses.

(m) *Status offense* means an offense which, if committed by an adult, would not be designated a crime under this part or under an ordinance of the tribe.

§ 11.901 The children's court established.

When conducting proceedings under §§ 11.900–11.1114 of this part, the Court of Indian Offenses shall be known as the "Children's Court".

§ 11.902 Non-criminal proceedings.

No adjudication upon the status of any minor in the jurisdiction of the children's court shall be deemed criminal or be deemed a conviction of a crime, unless the children's court refers the matter to the Court of Indian Offenses. Neither the disposition nor evidence given before the children's court shall be admissible as evidence against the child in any proceeding in another court.

§ 11.903 Presenting officer.

(a) The agency superintendent and the chief magistrate of the children's court shall jointly appoint a presenting officer to carry out the duties and responsibilities set forth under §§ 11.900–11.1114 of this part. The presenting officer's qualifications shall be the same as the qualifications for the official who acts as prosecutor for the Court of Indian Offenses. The presenting officer may be the same person who acts as prosecutor in the Court of Indian Offenses.

(b) The presenting officer shall represent the tribe in all proceedings under §§ 11.900–11.1114 of this part.

§ 11.904 Guardian ad litem.

The children's court, under any proceeding authorized by this part, shall appoint, for the purposes of the proceeding, a guardian ad litem for a minor, where the court finds that the minor does not have a natural or adoptive parent, guardian or custodian willing and able to exercise effective guardianship, or where the parent, guardian, or custodian has been accused of abusing or neglecting the minor.

§ 11.905 Jurisdiction.

The children's court has exclusive, original jurisdiction of the following proceedings:

(a) Proceedings in which a minor who resides in a community for which the court is established is alleged to be a juvenile offender, unless the children's court transfers jurisdiction to the Court of Indian Offenses pursuant to § 11.907 of this part.

(b) Proceedings in which a minor who resides in a community for which the court is established is alleged to be a minor-in-need-of-care.

§ 11.906 Rights of parties.

(a) In all hearings and proceedings under §§ 11.900–11.1114 of this part the following rights will be observed unless modified by the particular section describing a hearing or proceeding:

(1) Notice of the hearing or proceeding shall be given the minor, his or her parents, guardian or custodian and their counsel. The notice shall be delivered by certified mail. The notice shall contain:

(i) The name of the court;

(ii) The title of the proceeding; and

(iii) The date, time and place of the proceeding.

(b) The children's court magistrate shall inform the minor and his or her parents, guardian or custodian of their right to retain counsel, and, in juvenile delinquency proceedings, shall tell them: "You have a right to have a lawyer or other person represent you at this proceeding. If you cannot afford to hire counsel, the court will appoint counsel for you."

(c) If the children's court magistrate believes there is a potential conflict of interest between the minor and his or her parents, guardian, or custodian with respect to legal representation, the court shall appoint another person to act as counsel for the minor.

(d) The minor need not be a witness against, nor otherwise incriminate, himself or herself.

(e) The children's court shall give the minor, and the minor's parent, guardian or custodian the opportunity to introduce evidence, to be heard on their own behalf and to examine witnesses.

§ 11.907 Transfer to Court of Indian Offenses.

(a) The presenting officer or the minor may file a petition requesting the children's court to transfer the minor to the Court of Indian Offenses if the minor is 14 years of age or older and is alleged to have committed an act that would have been considered a crime if committed by an adult.

(b) The children's court shall conduct a hearing to determine whether jurisdiction of the minor should be transferred to the Court of Indian Offenses.

(1) The transfer hearing shall be held no more than 30 days after the petition is filed.

(2) Written notice of the transfer hearing shall be given to the minor and the minor's parents, guardian or custodian at least 72 hours prior to the hearing.

(c) All the rights listed in § 11.906 shall be afforded the parties at the transfer hearing.

(d) The following factors shall be considered when determining whether to transfer jurisdiction of the minor to the Court of Indian Offenses:

(1) The nature and seriousness of the offense with which the minor is charged.

(2) The nature and condition of the minor, as evidenced by his or her age; mental and physical condition; past record of offenses; and responses to past children's court efforts at rehabilitation.

(e) The children's court may transfer jurisdiction of the minor to the Court of Indian Offenses if the children's court finds clear and convincing evidence that both of the following circumstances exist:

(1) There are no reasonable prospects for rehabilitating the minor through resources available to the children's court; and

(2) The offense allegedly committed by the minor evidences a pattern of

conduct which constitutes a substantial danger to the public.

(f) When a minor is transferred to the Court of Indian Offenses, the children's court shall issue a written transfer order containing reasons for its order. The transfer order constitutes a final order for purposes of appeal.

§ 11.908 Court records.

(a) A record of all hearings under §§ 11.900–11.1114 of this part shall be made and preserved.

(b) All children's court records shall be confidential and shall not be open to inspection to anyone but the minor, the minor's parents or guardian, the presenting officer, or others by order of the children's court.

§ 11.909 Law enforcement records.

(a) Law enforcement records and files concerning a minor shall be kept separate from the records and files of adults.

(b) All law enforcement records and files shall be confidential and shall not be open to inspection to anyone but the minor, the minor's parents or guardian, the presenting officer, or others by order of the children's court.

§ 11.910 Expungement.

When a minor who has been the subject of any proceeding before the children's court attains his or her twenty-first birthday, the children's court magistrate shall order the court records and the law enforcement records pertaining to the minor to be destroyed, except for adoption records which shall not be destroyed under any circumstances.

§ 11.911 Appeal.

(a) For purposes of appeal, a record of the proceedings shall be made available to the minor and parents, guardian or custodian. Costs of obtaining the record shall be paid by the party seeking the appeal.

(b) Any party to a children's court hearing may appeal a final order or disposition of the case by filing a written notice of appeal with the children's court within 30 days of the final order of disposition.

(c) No decree or disposition of a hearing shall be stayed by such appeal.

(d) All appeals shall be conducted in accordance with this part.

§ 11.912 Contempt of court.

Any willful disobedience or interference with any order of the children's court constitutes contempt of court which may be punished in accordance with this part.

Subpart J—Juvenile Offender Procedure

§ 11.1000 Complaint.

A complaint must be filed by a law enforcement officer or by the presenting officer and sworn to by a person who has knowledge of the facts alleged. The complaint shall be signed by the complaining witness, and shall contain:

(a) A citation to the specific section(s) of this part which gives the children's court jurisdiction of the proceedings;

(b) A citation to the section(s) of this part which the minor is alleged to have violated;

(c) The name, age, and address of the minor who is the subject of the complaint, if known; and

(d) A plain and concise statement of the facts upon which the allegations are based, including the date, time, and location at which the alleged facts occurred.

§ 11.1001 Warrant.

The children's court may issue a warrant directing that a minor be taken into custody if the court finds there is probable cause to believe the minor committed the delinquent act alleged in the complaint.

§ 11.1002 Custody.

A minor may be taken into custody by a law enforcement officer if:

(a) The officer observes the minor committing a delinquent act; or

(b) The officer has reasonable grounds to believe a delinquent act has been committed that would be a crime if committed by an adult, and that the minor has committed the delinquent act; or

(c) A warrant pursuant to § 11.1001 has been issued for the minor.

§ 11.1003 Law enforcement officer's duties.

A law enforcement officer who takes a minor into custody pursuant to § 11.1002 of this part shall:

(a) Give the following warnings to any minor taken into custody prior to any questioning:

(1) The minor has a right to remain silent;

(2) Anything the minor says can be used against the minor in court;

(3) The minor has the right to the presence of counsel during questioning; and

(4) If he or she cannot afford counsel, the court will appoint one.

(b) Release the minor to the minor's parent, guardian, or custodian and issue a verbal advice or warning as may be appropriate, unless shelter care or detention is necessary.

(c) If the minor is not released, make immediate and recurring efforts to notify the minor's parents, guardian, or custodian to inform them that the minor has been taken into custody and inform them of their right to be present with the minor until an investigation to determine the need for shelter care or detention is made by the court.

§ 11.1004 Detention and shelter care.

(a) A minor alleged to be a juvenile offender may be detained, pending a court hearing, in the following places:

(1) A foster care facility approved by the tribe;

(2) A detention home approved by the tribe; or

(3) A private family home approved by the tribe.

(b) A minor who is 16 years of age or older may be detained in a jail facility used for the detention of adults only if:

(1) A facility in paragraph (a) of this section is not available or would not assure adequate supervision of the minor;

(2) The minor is housed in a separate room from the detained adults; and

(3) Routine inspection of the room where the minor is housed is conducted every 30 minutes to assure his or her safety and welfare.

§ 11.1005 Preliminary inquiry.

(a) If a minor is placed in detention or shelter care, the children's court shall conduct a preliminary inquiry within 24 hours for the purpose of determining:

(1) Whether probable cause exist to believe the minor committed the alleged delinquent act; and

(2) Whether continued detention or shelter care is necessary pending further proceedings.

(b) If a minor has been released to the parents, guardian or custodian, the children's court shall conduct a preliminary inquiry within three days after receipt of the complaint for the sole purpose of determining whether probable cause exists to believe the minor committed the alleged delinquent act.

(c) If the minor's parents, guardian or custodian is not present at the preliminary inquiry, the children's court shall determine what efforts have been made to notify and to obtain the presence of the parents, guardian, or custodian. If it appears that further efforts are likely to produce the parents, guardian or custodian, the children's court shall recess for no more than 24 hours and direct that continued efforts be made to obtain the presence of parents, guardian or custodian.

(d) All the rights listed in § 11.906 shall be afforded the parties in a preliminary inquiry.

(e) The children's court shall hear testimony concerning:

(1) The circumstances that gave rise to the complaint or the taking of the minor into custody; and

(2) The need for detention or shelter care.

(f) If the children's court finds that probable cause exists to believe the minor performed the delinquent act, the minor shall be released to the parents, guardian or custodian, and ordered to appear at the adjudicatory hearing unless:

(1) The act is serious enough to warrant continued detention or shelter care;

(2) There is reasonable cause to believe the minor will run away and be unavailable for further proceedings; or

(3) There is reasonable cause to believe that the minor will commit a serious act causing damage to person or property.

(g) The children's court may release a minor pursuant to paragraph (f) of this section to a relative or other responsible adult tribal member if the parent, guardian, or custodian of the minor consents to the release. If the minor is ten years of age or older, the minor and the parents, guardian or custodian must both consent to the release.

(h) Upon a finding that probable cause exists to believe that the minor has committed the alleged delinquent act and that there is need for detention or shelter care, the minor's detention or shelter care shall be continued. Otherwise, the complaint shall be dismissed and the minor released.

§ 11.1006 Investigation by the presenting officer.

(a) The presenting officer shall make an investigation following the preliminary inquiry or the release of the minor to his or her parents, guardian or custodian to determine whether the interests of the minor and the public require that further action be taken. Upon the basis of this investigation, the presenting officer may:

(1) Determine that no further action be taken;

(2) Begin transfer proceedings to the Court of Indian Offenses pursuant to § 11.907 of this part; or

(3) File a petition pursuant to § 11.1007 of this part to initiate further proceedings. The petition shall be filed within 48 hours of the preliminary inquiry if the minor is in detention or shelter care. If the minor has been previously released to his or her parents, guardian or custodian, relative or responsible adult, the petition shall be filed within ten days of the preliminary inquiry.

§ 11.1007 Petition.

(a) Proceedings under §§ 11.1000–11.1014 of this part shall be instituted by a petition filed by the presenting officer on behalf of the tribe and in the interests of the minor. The petition shall state:

(1) The name, birth date, and residence of the minor;

(2) The names and residences of the minor's parents, guardian or custodian;

(3) A citation to the specific section(s) of this part which gives the children's court jurisdiction of the proceedings;

(4) A citation to the section(s) of this part which the minor is alleged to have violated; and

(5) If the minor is in detention or shelter care, the time the minor was taken into custody.

§ 11.1008 Date of hearing.

Upon receipt of the petition, the children's court shall set a date for the hearing which shall not be more than 15 days after the children's court receives the petition from the presenting officer. If the adjudicatory hearing is not held within 15 days after filing of the petition, the petition shall be dismissed and cannot be filed again, unless;

(a) The hearing is continued upon motion of the minor; or

(b) The hearing is continued upon motion of the presenting officer by reason of the unavailability of material evidence or witnesses and the children's court finds the presenting officer has exercised due diligence to obtain the material evidence or witnesses and reasonable grounds exist to believe that the material evidence or witnesses will become available.

§ 11.1009 Summons.

(a) At least five working days prior to the adjudicatory hearing, the children's court shall issue summons to:

(1) The minor;

(2) The minor's parents, guardian or custodian; and

(3) Any person the children's court or the minor believes necessary for the adjudication of the hearing.

(b) The summons shall contain the name of the court, the title of the proceedings, and the date, time and place of the hearing.

(c) A copy of the petition shall be attached to the summons.

(d) The summons shall be delivered personally by a law enforcement officer or appointee of the children's court. If the summons cannot be delivered personally, the court may deliver it by certified mail.

§ 11.1010 Adjudicatory hearing.

(a) The children's court shall conduct the adjudicatory hearing for the sole purpose of determining the guilt or innocence of the minor. The hearing shall be private and closed.

(b) All the rights listed in § 11.906 shall be afforded the parties at the adjudicatory hearing. The notice requirements of § 11.906(a) are met by a summons issued pursuant to § 11.1009.

(c) If the minor admits the allegations of the petition, the children's court shall proceed to the dispositional stage only if the children's court finds that:

(1) The minor fully understands his or her rights as set forth in § 11.906 of this part and fully understands the potential consequences of admitting the allegations;

(2) The minor voluntarily, intelligently and knowingly admits to all facts necessary to constitute a basis for children's court action; and

(3) The minor has not, in the purported admission to the allegations, set forth facts which, if found to be true, constitute a defense to the allegations.

(d) The children's court shall hear testimony concerning the circumstances which gave rise to the complaint.

(e) If the allegations of the petition are sustained by proof beyond a reasonable doubt, the children's court shall find the minor to be a juvenile offender and proceed to the dispositional hearing.

(f) A finding that a minor is a juvenile offender constitutes a final order for purposes of appeal.

§ 11.1011 Dispositional hearing.

(a) A dispositional hearing shall take place not more than 15 days after the adjudicatory hearing.

(b) At the dispositional hearing, the children's court shall hear evidence on the question of proper disposition.

(c) All the rights listed in § 11.906 shall be afforded the parties in the dispositional hearing.

(d) At the dispositional hearing, the children's court shall consider any predisposition report, physician's report or social study it may have ordered and afford the parents an opportunity to controvert the factual contents and conclusions of the reports. The children's court shall also consider the alternative predisposition report prepared by the minor and his or her attorney, if any.

(e) The dispositional order constitutes a final order for purposes of appeal.

§ 11.1012 Dispositional alternatives.

(a) If a minor has been adjudged a juvenile offender, the children's court may make the following disposition:

(1) Place the minor on probation subject to conditions set by the children's court;

(2) Place the minor in an agency or institution designated by the children's court; or

(3) Order restitution to the aggrieved party.

(b) The dispositional orders are to be in effect for the time limit set by the children's court, but no order may continue after the minor reaches 18 years of age, unless the dispositional order was made within six months of the minor's eighteenth birthday or after the minor had reached 18 years of age, in which case the disposition may not continue for more than six months.

(c) The dispositional order is to be reviewed at the children's court discretion, but at least once every six months.

§ 11.1013 Modification of dispositional order.

(a) A dispositional order of the children's court may be modified upon a showing of a change of circumstances.

(b) The children's court may modify a dispositional order at any time upon the motion of the minor or the minor's parents, guardian or custodian.

(c) If the modification involves a change of custody, the children's court shall conduct a hearing pursuant to paragraph (d) of this section.

(d) A hearing to review a dispositional order shall be conducted as follows:

(1) All the rights listed in § 11.906 shall be afforded the parties in the hearing to review the dispositional order. The notice required by paragraph (a) of § 11.906 shall be given at least 48 hours before the hearing.

(2) The children's court shall review the performance of the minor, the minor's parents, guardian or custodian, and other persons providing assistance to the minor and the minor's family.

(3) In determining modification of disposition, the procedures prescribed in § 11.1011 of this part shall apply.

(4) If the request for review of disposition is based upon an alleged violation of a court order, the children's court shall not modify its dispositional order unless it finds clear and convincing evidence of the violation.

§ 11.1014 Medical examination.

The children's court may order a medical examination for a minor who is alleged to be a juvenile offender.

Subpart K—Minor-in-Need-of-Care Procedure

§ 11.1100 Complaint.

A complaint must be filed by a law enforcement officer or by the presenting officer and sworn to by a person who has knowledge of the facts alleged. The complaint shall be signed by the complaining witness and shall contain:

(a) A citation to the specific section of this part which gives the children's court jurisdiction of the proceedings;

(b) The name, age and address of the minor who is the subject of the complaint, if known; and

(c) A plain and concise statement of the facts upon which the allegations are based, including the date, time and location at which the alleged facts occurred.

§ 11.1101 Warrant.

The children's court may issue a warrant, directing that a minor be taken into custody if the children's court finds there is probable cause to believe the minor is a minor-in-need-of-care.

§ 11.1102 Custody.

A minor may be taken into custody by a law enforcement officer if:

(a) The officer has reasonable grounds to believe that the minor is a minor-in-need-of-care and that the minor is in immediate danger from his or her surroundings and that removal is necessary; or

(b) A warrant pursuant to § 11.1101 of this part has been issued for the minor.

§ 11.1103 Law enforcement officer's duties.

Upon taking a minor into custody the officer shall:

(a) Release the minor to the minor's parents, guardian or custodian and issue a verbal advice or warning as may be appropriate, unless shelter care is necessary.

(b) If the minor is not released, make immediate and recurring efforts to notify the minor's parents, guardian or custodian to inform them that the minor has been taken into custody and inform them of their right to be present with the minor until an investigation to determine the need for shelter care is made by the children's court.

§ 11.1104 Shelter care.

(a) A minor alleged to be a minor-in-need-of-care may be detained, pending a court hearing, in the following places:

(1) A foster care facility authorized under tribal or state law to provide foster care, group care or protective residence;

(2) A private family home approved by the tribe; or

(3) A shelter care facility operated by a licensed child welfare services agency and approved by the tribe.

(b) A minor alleged to be a minor-in-need-of care may not be detained in a jail or other facility used for the detention of adults. If such minor is detained in a facility used for the detention of juvenile offenders, he or she must be detained in a room separate from juvenile offenders, and routine inspection of the room where the minor is detained must be conducted every 30 minutes to assure his or her safety and welfare.

§ 11.1105 Preliminary inquiry.

(a) If a minor is placed in shelter care, the children's court shall conduct a preliminary inquiry with 24 hours for the purpose of determining:

(1) Whether probable cause exists to believe the minor is a minor-in-need-of care; and

(2) Whether continued shelter care is necessary pending further proceedings.

(b) If a minor has been released to the parents, guardian or custodian, the children's court shall conduct a preliminary inquiry within three days after receipt of the complaint for the sole purpose of determining whether probable cause exists to believe the minor is a minor-in-need-of-care.

(c) If the minor's parents, guardian or custodian is not present at the preliminary inquiry, the children's court shall determine what efforts have been made to notify and obtain the presence of the parent, guardian or custodian. If it appears that further efforts are likely to produce the parent, guardian or custodian, the children's court shall recess for no more than 24 hours and direct that continued efforts be made to obtain the presence of the parents, guardian or custodian.

(d) All the rights listed in § 11.906 of this part shall be afforded the parties in the minor-in-need-of care preliminary inquiry except that the court is not required to appoint counsel if the parties cannot afford one. Notice of the inquiry shall be given to the minor, and his or her parents, guardian or custodian and their counsel as soon as the time for the inquiry has been established.

(e) The children's court shall hear testimony concerning:

(1) The circumstances that gave rise to the complaint or the taking of the minor into custody; and

(2) The need for shelter care.

(f) If the children's court finds that probable cause exists to believe the minor is a minor-in-need-of-care, the minor shall be released to the parents, guardian or custodian, and ordered to appear at the adjudicatory hearing, unless:

(1) There is reasonable cause to believe that the minor will run away and be unavailable for further proceedings;

(2) There is reasonable cause to believe that the minor is in immediate danger from parents, guardian or

custodian and that removal from them is necessary; or

(3) There is a reasonable cause to believe that the minor will commit a serious act causing damage to person or property.

(g) The children's court may release the minor pursuant to paragraph (f) of this section to a relative or other responsible adult tribal member if the parents, guardian or custodian of the minor consent to the release. If the minor is ten years to age or older, the minor and the parents, guardian or custodian must both consent to the release.

(h) Upon finding that probable cause exists to believe that the minor is a minor-in-need-of-care and that there is a need for shelter care, the minor's shelter care shall be continued. Otherwise, the complaint shall be dismissed and the minor released.

§ 11.1106 Investigation by the presenting officer.

The presenting officer shall make an investigation following the preliminary inquiry or the release of the minor to the parents, guardian or custodian to determine whether the interests of the minor and the public require that further action be taken. Upon the basis of this investigation, the presenting officer may:

(a) Determine that no further action be taken; or

(b) File a petition pursuant to § 11.1107 of this part in the children's court to initiate further proceedings. The petition shall be filed within 48 hours of the preliminary inquiry if the minor is in shelter care. If the minor has been previously released to the parents, guardian or custodian, relative or responsible adult, the petition shall be filed within ten days of the preliminary inquiry.

§ 11.1107 Petition.

Proceedings under §§ 11.1100–11.1114 of this part shall be instituted by a petition filed by the presenting officer on behalf of the tribe and the interests of the minor. The petition shall state:

(a) The name, birth date, and residence of the minor;

(b) The names and residences of the minor's parents, guardian or custodian;

(c) A citation to the specific section of this part which gives the children's court jurisdiction of the proceedings; and

(d) If the minor is in shelter care, the place of shelter care and the time he or she was taken into custody.

§ 11.1108 Date of hearing.

Upon receipt of the minor-in-need-of-care petition, the children's court shall set a date for the hearing which shall not be more than 15 days after the children's court receives the petition from the presenting officer. If the adjudicatory hearing is not held within 15 days after the filing of the petition, it shall be dismissed unless;

(a) The hearing is continued upon motion of the minor; or

(b) The hearing is continued upon motion of the presenting officer by reason of the unavailability of material evidence or witnesses and the children's court finds the presenting officer has exercised due diligence to obtain the material evidence or witnesses and reasonable grounds exist to believe that the material evidence or witnesses will become available.

§ 11.1109 Summons.

(a) At least five working days prior to the adjudicatory hearing for a minor-in-need-of-care, the children's court shall issue summons to:

(1) The minor;

(2) The minor's parents, guardian or custodian; and

(3) Any person the children's court or the minor believes necessary for the proper adjudication of the hearing.

(b) The summons shall contain the name of the court; the title of the proceedings, and the date, time and place of the hearing.

(c) A copy of the petition shall be attached to the summons.

(d) The summons shall be delivered personally by a tribal law enforcement officer or appointee of the children's court. If the summons cannot be delivered personally, the court may deliver it by certified mail.

§ 11.1110 Minor-in-need-of-care adjudicatory hearing.

(a) The children's court shall conduct the adjudicatory hearing for the sole purpose of determining whether the minor is a minor-in-need-of-care. The hearing shall be private and closed.

(b) All the rights listed in § 11.906 of this part shall be afforded the parties in the adjudicatory hearing, except that the court may not appoint counsel if the parties cannot afford one. The notice requirements of § 11.906(a) are met by a summons issued pursuant to § 11.1109.

(c) The children's court shall hear testimony concerning the circumstances which gave rise to the complaint.

(d) If the circumstances of the petition are sustained by clear and convincing evidence, the children's court shall find the minor to be a minor-in-need-of-care and proceed to the dispositional hearing.

(e) A finding that a minor is a minor-in-need-of-care constitutes a final order for purposes of appeal.

§ 11.1111 Minor-in-need-of-care dispositional hearing.

(a) No later than 15 days after the adjudicatory hearing, a dispositional hearing shall take place to hear evidence on the question of proper disposition.

(b) All the rights listed in § 11.906 of this part shall be afforded the parties in the dispositional hearing except the right to free court-appointed counsel. Notice of the hearing shall be given to the parties at least 48 hours before the hearing.

(c) At the dispositional hearing the children's court shall consider any predisposition report or other study it may have ordered and afford the parties an opportunity to controvert the factual contents and conclusions of the reports. The children's court shall also consider the alternative predisposition report prepared by the minor and his or her attorney, if any.

(d) The dispositional order constitutes a final order for purposes of appeal.

§ 11.1112 Dispositional alternatives.

(a) If a minor has been adjudged a minor-in-need-of-care, the children's court may:

(1) Permit the minor to remain with his or her parents, guardian or custodian subject to such limitations and conditions as the court may prescribe; or, if reasonable efforts to have the minor return or remain in his or her own home are unsuccessful, the children's court may make whichever of the following dispositions is in the best interest of the minor;

(2) Place the minor with a relative within the boundaries of the reservation subject to such limitations and conditions as the court may prescribe;

(3) Place the minor in a foster home within the boundaries of the reservation which has been approved by the tribe subject to such limitations and conditions as the court may prescribe;

(4) Place the minor in shelter care facilities designated by the court;

(5) Place the minor in a foster home or a relative's home outside the boundaries of the reservation subject to such limitations and conditions as the court may prescribe; or

(6) Recommend that termination proceedings begin.

(b) Whenever a minor is placed in a home or facility located outside the boundaries of the reservation, the court may require the party receiving custody of the minor to sign an agreement that the minor will be returned to the court upon order of the court.

(c) The dispositional orders are to be in effect for the time limit set by the children's court, but no order may continue after the minor reaches 18 years of age, unless the dispositional order was made within six months of the minor's eighteenth birthday, in which case the disposition may not continue for more than six months.

(d) The dispositional orders are to be reviewed at the children's court discretion, but at least once every six months to determine the continuing need for and appropriateness of placement, to determine the extent of progress made, and to assess the probability of the minor's return to his or her home.

(e) A permanency planning hearing must be held within 18 months after the original placement and every six months thereafter to determine the future status of the minor except when the minor is returned to his or her home and court supervision ceases.

§ 11.1113 Modification of dispositional order.

(a) A dispositional order of the children's court may be modified upon a showing of a change of circumstances.

(b) The children's court may modify a dispositional order at any time upon motion of the minor or the minor's parents, guardian or custodian.

(c) If the modification involves a change of custody, the children's court shall conduct a hearing pursuant to paragraph (d) of this section to review the dispositional order.

(d) A hearing to review a dispositional order shall be conducted as follows:

(1) All the rights listed in § 11.906 of this part shall be afforded the parties in the review of the disposition hearing except the right to free court-appointed counsel. Notice of the hearing shall be given the parties at least 48 hours before the hearing.

(2) The children's court shall review the performance of the minor, the minor's parents, guardian or custodian, and other persons providing assistance to the minor and the minor's family.

(3) In determining modification of disposition, the procedures prescribed in § 11.1111 of this part shall apply.

(4) If the request for review of disposition is based upon an alleged violation of a court order, the children's court shall not modify its dispositional order unless it finds clear and convincing evidence of the violation.

§ 11.1114 Termination.

(a) Parental rights to a child may be terminated by the children's court according to the procedures in this section.

(b) Proceedings to terminate parental rights shall be instituted by a petition filed by the presenting officer on behalf of the tribe or by the parents or guardian of the child. The petition shall state:

(1) The name, birth date, and residence of the minor;

(2) The names and residences of the minor's parents, guardian or custodian;

(3) If the child is in detention or shelter care, the place of detention or shelter care and the time he was taken into custody; and

(4) The reasons for the petition.

(c) Upon receipt of the petition, the children's court shall set a date for the termination hearing which shall not be more than 15 days after the children's court receives the petition from the presenting officer. The hearing may be continued:

(1) On motion of the minor's parents, guardian or custodian; or

(2) Upon motion of the presenting officer by reason of the unavailability of material evidence or witnesses and the children's court finds the presenting officer has exercised due diligence to obtain the material evidence or witnesses and reasonable grounds exist to believe that the material evidence or witnesses will become available.

(d) Summons:

(1) At least five working days prior to the termination hearing, the children's court shall issue summons to the minor, the minor's parents, guardian or custodian, and any other person the court or the minor's parents, guardian or custodian believes necessary for the proper adjudication of the hearing.

(2) The summons shall contain the name of the court, the title of the proceedings, and the date, time and place of the hearing.

(3) A copy of the petition shall be attached to the summons.

(4) The summons shall be delivered personally by a law enforcement officer or appointee of the children's court. If the summons cannot be delivered personally, the court may deliver it by certified mail.

(e) The children's court shall conduct the termination hearing for the sole purpose of determining whether parental rights shall be terminated. The hearing shall be private and closed.

(1) All the rights listed in § 11.906 shall be afforded the parties in the termination hearing except the right to a free court-appointed counsel. The minor's parents may not be compelled to be witnesses against, nor otherwise incriminate themselves.

(2) The children's court shall hear testimony concerning the circumstances that gave rise to the petition, and the need for termination of parental rights.

(3) The children's court may terminate parental rights if, following efforts to prevent or eliminate the need to remove the minor, it finds such efforts to have been unsuccessful, and it finds beyond a reasonable doubt that:

(i) The child has been abandoned;

(ii) The minor has suffered physical injuries, willfully and repeatedly inflicted by his or her parent(s) which cause or create a substantial risk of death, disfigurement, or impairment of bodily functions;

(iii) The parent(s) has subjected the minor to willful and repeated acts of sexual abuse;

(iv) The minor has suffered serious emotional or mental harm due to the act of the parent(s); or

(v) The voluntary written consent of both parents has been acknowledged before the court.

(f) Dispositional alternatives:

(1) If parental rights to a child are terminated, the children's court shall place the minor in a foster care or shelter care facility which has been approved by the tribe, and follow the adoption procedures of the tribe, or, in their absence, the adoption procedures of the state within which it is located.

(2) If parental rights to a child are not terminated, the children's court shall make a disposition according to § 11.1112 of this part.

(g) The termination order constitutes a final order for purposes of appeal.

(h) No adjudication of termination of parental rights shall affect the minor's enrollment status as a member of any tribe or the minor's degree of blood quantum of any tribe.

§ 11.1115 Information collection.

(a) The information collection requirements contained in § 11.600 and § 11.606 have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*, and assigned approval number 1076–0094. The information is being collected to obtain a marriage license (§ 11.600) and a divorce decree (§ 11.606) from the Courts of Indian Offenses, and will be used by the courts to issue a marriage license or divorce decree. Response to this request is required to obtain a benefit.

(b) Public reporting for this information collection is estimated to average .25 hours per response, including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the information collection. Direct comments regarding the burden estimate or any other aspect of this information collection to the Bureau of Indian Affairs, Information Collection

Clearance Officer, Room 336–SIB, 1849 C Street, NW., Washington, DC 20240; and the Office of Information and Regulatory Affairs [Project 1076–0094], Office of Management and Budget, Washington, DC 20502.

3. A new part 12, The Indian Police, is added, containing newly redesignated §§ 12.100 through 12.105. The table of contents and authority for the new part 12 are as follows:

PART 12—THE INDIAN POLICE

Sec. 12.100 Superintendent in command.
Sec. 12.101 Police commissioners.
Sec. 12.102 Police training.
Sec. 12.103 Minimum standards for police programs.
Sec. 12.104 Minimum standards for detention programs.
Sec. 12.105 Return of equipment.

Authority: 25 U.S.C. 2, 13.

Woodrow W. Hopper, Jr.,

Acting Assistant Secretary, Indian Affairs.

[FR Doc. 93–25714 Filed 10–20–93; 8:45 am]

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Federal Register

Thursday
October 21, 1993

Part III

Department of Education

Educational Media Research, Production, Distribution, and Training Program; Notices

DEPARTMENT OF EDUCATION

Educational Media Research, Production, Distribution, and Training Program

AGENCY: Department of Education.

ACTION: Notice of final funding priorities for fiscal year 1994.

SUMMARY: The Secretary announces funding priorities for fiscal year 1994 under the Educational Media Research, Production, Distribution, and Training Program. The Secretary takes this action to focus Federal financial assistance on those areas of greatest need. These priorities are intended to ensure the continued availability of closed-captioned television sports programming, expand on the number and types of video-described projects, include research on video description and research on captioning technology as a language development tool, continue the video captioning process, and explore the future direction of captioned media programs.

EFFECTIVE DATE: These priorities take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments. If you want to know the effective date of these priorities, call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT: Ernest E. Hairston, U.S. Department of Education, 400 Maryland Avenue SW., room 4629, Switzer Building, Washington, DC 20202–2644. Telephone: (202) 205–9172. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–8169; or the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: This notice contains seven priorities under the Educational Media Research, Production, Distribution, and Training Program authorized under part F of the Individuals with Disabilities Education Act (IDEA). The purposes of the program are to promote the general welfare of deaf and hard of hearing individuals and individuals with visual impairments, and to promote the educational advancement of individuals with disabilities.

One priority in this notice provides cooperative agreements to ensure the continued availability of closed-captioned sports programming. In addition, other priorities will expand on the number and types of video-described projects to include (1) broadcast and cable video description, (2) described home videos, and (3) research on video description. These priorities will also provide (1) research on captioning technology as a language development tool and (2) a symposium to explore the future directions of captioned media programs.

An additional priority in this notice provides for a cooperative agreement to assist in the provision of video captioning services such as obtaining, screening, evaluating, and captioning educational videos and related media.

These priorities support the National Education Goals by assisting those with disabilities in meeting Goal 1, school readiness, and Goal 5, adult literacy.

On June 23, 1993 the Secretary published a notice of proposed priorities in the **Federal Register** (58 FR 34168).

Note: This notice of final priorities does not solicit applications. A notice inviting applications under this program is published in a separate notice in this issue of the **Federal Register.**

Analysis of Comments and Changes

In response to the Secretary's invitation in the notice of proposed priorities, twenty-one parties submitted comments. An analysis of the comments and of changes in the priorities since publication of the notice of the proposed priorities follows. Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under applicable statutory authority—are not addressed.

General

Comment: Two commenters urged the Secretary to make more than one award under the various priorities in order to continue to generate private sector support or to increase competition.

Discussion: In announcing priorities, the Secretary does not generally establish numbers of awards unless it is critical to the activities included under the priority.

Changes: The specified number of projects has been dropped from priorities two and three, thereby allowing for the possibility of more than one award.

Comment: Three commenters recommended a priority for captioned videos, and one suggested deleting the priority for described videos.

Discussion: The Secretary recognizes the importance of captioned videos, and supports it under activities described in Priority 7. The Secretary also recognizes the importance of video description for persons with visual impairments and the need for continued support of this activity which is not currently supported through other sources.

Changes: None.

Comment: Four commenters indicated an interest in support for closed-captioning of basic cable television programming.

Discussion: The Secretary recognizes the importance of access to programs shown on local stations, national commercial and public broadcast networks, as well as syndicated and cable programs shown nationally. In making awards the Secretary will continue to support the closed-captioning of basic cable television programming under activities such as Priority 1 of this notice as well as under several current awards.

Changes: None.

Comment: One commenter proposed a cooperative agreement for a series of deaf theatre arts festivals to share the wealth of talent, skill, and theatrical productions developed by grantees under the program during the past two years.

Discussion: The Secretary agrees that there is a need to systematically and broadly disseminate the rich cultural experiences being developed by the grantees. Although the priorities in this notice do not address this issue, consideration may be given to it or a similar vehicle for sharing experiences in future years.

Changes: None.

Comment: One commenter proposed a priority to support the videotape productions of original cultural programs by and for deaf and hard of hearing individuals. The priority would provide seed money to develop the productions. The dissemination of the videotapes would provide a wider audience of consumers access to quality cultural arts programming.

The commenter also proposed a priority to provide support for the development of videotape materials that deal with issues in mental and physical health affecting deaf and hard of hearing individuals. Videotapes would make use of innovative approaches to portray deaf and hard of hearing persons dealing with these issues and identifying possible solutions.

Discussion: The Secretary agrees that there is merit in producing a varied set of videotapes geared toward deaf and hard of hearing individuals, as well as those with other disabilities. However, the activities described in these final priorities are of even greater importance if individuals with disabilities are to have continued access to existing media.

Changes: None.

Absolute Priority 1—Closed-Captioned Sports Programs

Comment: One commenter requested that the Secretary add to this priority specific language giving preference to continued captioning of sports programs currently captioned as well as language to indicate inclusion of specific types of cable programming (i.e., basic, premium, and pay-per-view).

Discussion: The Secretary is not inclined to give preference to currently captioned sports programs because programs that have been previously captioned may have been captioned as the result of program availability, and not necessarily consumer preference. The Secretary wishes to give emphasis to consumer preference. Further, the priority as written encompasses all types of cable programming.

Changes: None.

Comment: One commenter suggested that priorities for captioning should focus on persuading networks and stations to assume a greater degree of responsibility for covering the cost of captioning.

Discussion: The Secretary agrees that increased private sector funding of closed-captioning is important. In fact, since 1980 the portion of captioning paid for through non-federal support has grown significantly, particularly in prime-time news and sports programming on major broadcast networks. The Secretary believes that as the implementation of the Decoder Circuitry Act increases the number of homes with decoders, this trend is likely to accelerate. Therefore, the Secretary believes there is no need at this time to add such a focus to the language of this priority.

Changes: None.

Absolute Priority 2—Broadcast and Cable Television Description and Absolute Priority 3—Described Home Video

Comment: One commenter requested a clarification regarding the requirement for identification of sources of private sector funding. The commenter urged that private funding not be made mandatory, stating that private sector funding was particularly difficult to obtain at this stage of development for description services.

Discussion: The Secretary does not intend to require private sector funding under this priority, but rather to encourage projects to seek any support that might become available.

Changes: Priorities two and three have been changed to indicate that sources of private or other public support for description, should any be available, must be identified.

Comment: Two commenters sought clarification of the methods used to provide description. Another commenter requested clarification of the difference between description for broadcast television and description for cable television. One commenter stated that commercial networks, included under this priority for the first time, may resist description because of the high cost of audio routing equipment for a separate description channel.

Discussion: Two examples of the current methods used for description are identified in the priority: One method uses the Secondary Audio Program (SAP), the other uses open description (similar to open captioning, where all viewers are subject to the descriptions). Public television has primarily broadcast descriptions using the SAP channel, although it has provided open descriptions upon occasion. Providers of video description for cable and home video have used open descriptions. However, the method to be used to provide description is not stipulated in the priority. The inclusion of the terms broadcast and cable within the priority is to indicate that programs on both types of networks may be included in the activities under this priority.

As with open captioning, the commercial networks may prefer not to broadcast open descriptions for regular programming because of overall viewer preference. Further, the Secretary agrees that commercial networks may also resist video description because of the high cost of audio routing equipment for a separate description channel. The priority does not stipulate that commercial broadcast networks must be included in the activities under this priority. The Secretary, however, does not wish to preclude commercial broadcast networks from the priority.

Changes: None.

Comment: One commenter expressed the concern that outreach was not identified as an activity in the priorities for video description.

Discussion: The Secretary agrees that outreach (marketing and dissemination) is a necessary component to approved projects for video description. All applications submitted to the Secretary under these priorities are evaluated under the established selection criteria at 34 CFR 332.32, which include information related to marketing and dissemination.

Changes: None.

Comment: One commenter expressed an interest in a priority for video description of televised sports.

Discussion: While the Secretary agrees that video description of televised sports may be of interest to persons with visual impairments, the Secretary believes that research is needed as to viewer demographics and interests before designating specific types of programs for description.

Changes: None.

Absolute Priority 4—Research on Video Description

Comment: Three commenters expressed an interest in promoting the educational benefits of descriptive video through research.

Discussion: The Secretary acknowledges the value of research on the educational benefits of descriptive video. The Secretary believes that this topic may be addressed as a related issue under the priority for Research on Video Description.

Changes: None.

Absolute Priority 5—Research on Captioning as a Language Development Tool

Comment: Three commenters strongly supported this priority and stated that it will extend opportunities for developing literacy skills, not only of students with other disabilities, but non-disabled children as well as those for whom English is a second language. One commenter encouraged the Department to broaden this priority to include research into the potential benefits of captioning as a preventive technique, thus covering individuals for whom English is a second language.

Discussion: The authorizing legislation and program regulations at 34 CFR 332.10 clearly state that projects funded under the Educational Media Research, Production, Distribution, and Training Program are to benefit individuals with disabilities. However, research findings and resulting benefits may be useful to other agencies or individuals serving specific populations.

Changes: None.

Comment: One commenter suggested that the word "standards," as used in the background information be replaced by the word "styles" because "standards" suggests an official process that overstates any current activities in this area.

Discussion: The Secretary agrees that the use of the term "standards" may be misleading.

Changes: "Styles" has been substituted for "standards."

Comment: One commenter indicated that a 18-month project period is not an adequate amount of time to refine the research design, conduct the study, and disseminate the results of the project, and recommended that research projects

be 24 months in length with 12-month extensions at the option of the Department.

Discussion: The priority did not specify any project period. The Secretary, however, agrees that a reasonable amount of time should be provided to allow researchers to adequately conduct research efforts. Information about project periods is provided in the Secretary's notice inviting application for new awards.

Changes: None.

Comment: One commenter pointed out that the priority did not mention dissemination of the results of studies or projects.

Discussion: The Secretary acknowledges the importance of disseminating project results. The program regulations at 34 CFR 332.41 require that all projects funded under the Educational Media Research, Production, Distribution, and Training Program disseminate their findings and products broadly.

Changes: None.

Comment: One commenter requested clarification on what was meant by the term "outcomes data" as referred to in paragraph (4) of the priority.

Discussion: The Secretary understands how the term "outcomes" can cause some confusion since it has also been used in reference to educational goals expected of students. However, under this priority the term is intended to mean any concrete or existing data that are collected or result from the research study. In other words, the term refers to actual rather than expected results.

Changes: None.

Comment: One commenter sought clarification on whether a project must conduct the research in more than one setting or more than one type of setting, as referred under paragraph (5) of the priority.

Discussion: The Secretary agrees with the commenter that depending on the population one intends to study or the nature of the study, one setting or type of setting may be appropriate. In establishing this requirement the Secretary intended to emphasize that the settings must be realistic and as natural as possible as opposed to being laboratory-like or in isolation. The settings listed are examples of settings that might be included in the research, but a particular project would not necessarily focus on more than one setting.

Changes: The words "a variety of" have been removed from the priority.

Comment: One commenter suggested that the educational/linguistic implications of caption capture technology be investigated as a tool in enhancing reading and language development.

Discussion: This priority allows projects to address the issues described in the priority or other issues related to captioning as a language development tool. Thus, research on caption capture technology could be included under this priority.

Changes: None.

Absolute Priority 6—Symposium on Exploring New Strategies for Providing Captioned Media Services

Comment: Three commenters expressed support for using a symposium format to study long-term strategies for expanding the availability of captioned media. One commenter objected to the emphasis on closed captions rather than on open captions, stating that the greatest percentage of deaf and hard of hearing students are in mainstream programs that might not have access to decoders.

Discussion: The Secretary did not intend for this priority to focus on any one method or form of captioning. The main purpose of the symposium is to explore as many strategies as possible to make captioned media available to as wide a number of deaf and hard of hearing individuals as possible. The term closed-captioning was used in reference to television programming that has been close-captioned.

Changes: None.

Comment: One commenter expressed concern regarding the lack of promotion and dissemination of the educational film and video lesson guides, and proposed that this issue be reviewed and discussed at the symposium. Several commenters suggested various additional pre-symposium activities or additional topics that should be included in the symposium. Other commenters suggested types of individuals that should be symposium attendees or presenters. One commenter suggested that attendance be free of charge and that the proceedings be distributed beyond the participants.

Discussion: The Secretary appreciates the commenters' suggestions and agrees that they could be taken into consideration by applicants responding to this priority. However, the Secretary does not believe this priority should be overly prescriptive. The successful applicant will be encouraged to consider various options in terms of participants, topics, and dissemination of conference proceedings.

Changes: None.

Absolute Priority 7—Educational Video Selection and Captioning

Comment: Twelve comments were received in support of this priority. Nine commenters expressed similar concerns regarding two areas: (1) closed-captioned educational videos and (2) the omission of the lesson guide production. Several pointed out that closed-captioned videos are not fully accessible nor desirable for educational purposes since many schools or programs do not have access to decoders. They also stated that the production of lesson guides has been a standard procedure for several years and has become an integral part of the program and serve a unique purpose. They suggested keeping this activity as an ongoing activity under this priority. One commenter supported the decision to leave out the lesson guide activity because of the low usage statistics, production limitations, and cost factors. The commenter offered support for the activity if these problems were resolved.

Discussion: The rationale and support for open-captioned educational videos is strong and convincing. The Secretary also recognizes the value of the lesson guides to educators who use them. However, the Secretary is also aware of the low usage, high cost factors, and complicated production logistics associated with the guides and believes the Department should evaluate this activity more closely before continuing this activity.

Through a separate mechanism the Secretary plans to review the impact of the lesson guides, teacher usage, and ensuing costs. If warranted, an activity for the development and production of lesson guides may be considered at a future date.

Changes: The priority has been changed to indicate that the educational videos procured for classroom use will include open-captioned and close-captioned videos for each title.

Comment: Three commenters indicated that many people do not know the difference between open, closed, and real-time captioning and know very little about the process. They suggested a clearinghouse that could disseminate captioning information to consumers, agencies, corporations, businesses and schools. Another commenter suggested that information on captioned videos from private databases be disseminated under this activity.

One commenter indicated that providers of new video formats and delivery systems (satellite, CD–ROM, and others) should be made aware of the benefits of captioned materials for other

special-needs groups, as well as for individuals with a hearing loss.

Discussion: The Secretary agrees with the importance of disseminating information about captioning, but believes the operation of a general clearinghouse on captioning or disseminating information from private databases is beyond the intended scope of this priority. Further, activities funded under this program are restricted to individuals who are deaf or hard of hearing. The Secretary will explore under other mechanisms ways to disseminate information about captioning to relevant organizations serving other special-needs groups.

Changes: None.

Comment: One commenter suggested that since advances in technology allow captions to be prepared on computers and since diskettes are used to transfer caption data directly to the finished product, the reference to preparation of captioned scripts is outmoded.

Discussion: The Secretary agrees with this observation.

Changes: This priority has been changed to require the preparation of captions on computer diskettes.

Comment: Two commenters indicated that in the past, the functions of two current contracts (one that parallels the activities under this priority) were under one contract and recommended that many of the current splintered and scattered activities be brought under this cooperative agreement. They suggested that the project evaluate, select, and caption new titles and also maintain a computer database of all video records, including production company, lease company, date of production, date of receipt in the program, lease expiration date, and lease documentation for continual coordination and follow-up with the video companies. Through this arrangement, commenters believe that the Captioned Film and Video Loan Service will more efficiently and effectively meet the needs of consumers.

Discussion: The Secretary will consider this recommendation at the same time the results and recommendations from the symposium under Priority 6 are considered.

Changes: None.

Comment: One commenter recommended that an extensive weeding process be initiated to eliminate theatrical, special interest, and educational titles that are no longer in demand or useful and convene re-evaluation groups and develop guidelines for withdrawing or replacing titles.

Discussion: The Secretary understands the importance of re-evaluating dated titles and withdrawing obsolete titles and replacing them with more current titles. This is included in the process of evaluating and selecting titles.

Changes: None.

Comment: One commenter recommended that a more broadly based evaluation of videos for captioning and inclusion in the theatrical and special interest collection should be included.

Discussion: The Secretary believes the evaluation process described in the priority will be more broadly based than similar activities in past years and allows for the inclusion of feature and special interest titles.

Change: None.

Comment: Two commenters thought the priority should address the issue of increased duplication from video masters of captioned educational and general interest titles. They anticipated an increasing demand for many titles by consumers because of the American with Disabilities Act (ADA), and stated that contract controlled duplication should be allowed to meet this increased demand.

Discussion: The Secretary is aware of the need to increase the number of duplicate copies of captioned video titles. This effort will be addressed through the process to procure the video titles.

Changes: None.

Comment: One commenter believed that work under the current contract has demonstrated the capability to select and caption 150 educational titles. Therefore, this individual recommended that the number of annual new educational title procurements be increased from 100 to 200–300 titles.

Discussion: The Secretary is pleased that technology and production systems are available to make it possible to caption an increased number of educational titles. The priority, as written, does not specify any given number. Applicants may propose a number they deem reasonable and practical.

Changes: None.

Comment: One commenter suggested that a consumer work group be convened biennially to provide input to the project, and that a similar advisory group of educators be a requirement.

Discussion: The priority as proposed requires strategies for determining the curricular needs of deaf and hard of hearing students as well as an evaluation program that incorporates consumer information into the selection and captioning process. Consumer advisory groups represent one approach to these requirements, and may be proposed by applicants under this program.

Changes: None.

Comment: One commenter suggested that making captioned videos available through general distribution mechanisms will require the Department to make distribution a prerequisite in the procurement of videos by the captioned film and video loan service.

Discussion: The Secretary will work closely with the successful applicant to determine what measures are necessary to make captioned videos available through general distribution mechanisms.

Changes: None.

Priorities

Under 34 CFR 75.105(c)(3) the Secretary gives an absolute preference to applications that meet the following priorities. The Secretary funds under these competitions only applications that meet these absolute priorities:

Absolute Priority 1—Closed-Captioned Sports Programs

Background: This priority supports cooperative agreements to continue and expand closed-captioning of major national sports programs shown on national commercial broadcast or cable television networks. Captioning provides a visual representation of the audio portion of the programming and enables persons who are deaf or hard of hearing to participate in the shared educational, social, and cultural experiences of national sporting events.

Priority: To be considered for funding under this priority, a project must—

(1) For selecting programs to be captioned, include criteria that take into account the preference of consumers for particular programs, the diversity of programming available, and the contribution of programs to the general educational, social, and cultural experiences of individuals with hearing impairments;

(2) Determine the total number of hours and the projected cost per hour for each program to be captioned;

(3) For each proposed program to be captioned, identify the source of private or other public support and the projected dollar amount of that support;

(4) Identify the methods of captioning to be used for each hour—indicating whether captioning is provided in real-time or offline—and the projected cost per hour for each method used;

(5) Provide and maintain back-up systems that would ensure successful, timely captioning service;

(6) Demonstrate the willingness of major national commercial broadcast or

cable networks to permit captioning of their programs; and

(7) Implement procedures for monitoring the extent to which full and accurate captioning is provided and use this information to make refinements in captioning operations.

Absolute Priority 2—Broadcast and Cable Television Description

Background: This priority supports cooperative agreements for the description of television programming shown on national commercial or public broadcast networks or cable networks, as well as syndicated programs, in order to make television programming more accessible to persons with visual impairments. The intent of this priority is to provide continued and expanded access to described television programming in order to enhance shared educational, social, and cultural experiences for persons who are visually impaired.

Currently, there are two types of described television available to persons with visual impairments: (1) WGBH's descriptive video services (DVS), which offers described video as part of its PBS programming, using the Second Audio Program (SAP) and (2) Narrative Television Network (NTN), which produces and airs described videos via the Nostalgia Channel cable service and affiliated stations. To date, commercial networks and local stations have been unwilling to broadcast described television (using the SAP) due to the required equipment modification and extensive equipment operations. Alternative approaches must be explored.

Priority: To be considered for funding under this priority, a project must—

(1) For selecting programs to be video described, include criteria that take into account the preference of consumers for particular programs, the diversity of programming available, and the contribution of programs to the general educational, social, and cultural experiences of individuals with visual impairments;

(2) Determine the total number of hours and the projected cost per hour for each program to be described;

(3) For each program to be described, identify the source of private or other public support, if any, and the projected dollar amount of that support;

(4) Identify the methods to be used in the provision of described video;

(5) Demonstrate the willingness of major national commercial or public broadcast networks or cable networks, as well as providers of syndicated programming, to permit video description of their programs; and

(6) Implement procedures for monitoring the extent to which an accurate description is provided and use this information to make refinements in the video description operations.

Absolute Priority 3—Described Home Video

Background: This priority supports cooperative agreements for describing and making available described home videos in order to enhance shared social, educational, and cultural experiences for persons who are visually impaired.

Priority: To be considered for funding under this priority, a project must—

(1) For selecting videos to be described, include criteria that take into account the preference of consumers for particular titles or subjects, the diversity of video titles available, and the contribution of the videos to the general social, educational, and cultural experience of individuals with visual impairments;

(2) Determine the total number of videos and the projected cost per original video to be described;

(3) For each proposed video to be described and made available, identify the source of private or other public support, if any, and the projected dollar amount of that support;

(4) Show evidence that copyright holders would permit video description and distribution of their videos;

(5) Identify strategies for making described home videos available to persons with visual impairments, including any public awareness activities used to inform persons with visual impairments about described home videos; and

(6) Evaluate the effectiveness of the methods and technologies used in providing this service, barriers encountered, and impact on intended populations.

Absolute Priority 4—Research on Video Description

Background: This priority supports research projects on video description services for persons who are visually impaired. Issues to be explored by projects funded under this priority would include, but not be limited to, the incidence of visual impairment within the general population; demographics of the target population; the extent of consumer interest in video description services; the degree of awareness of the availability of video description services; the percentage of visually impaired individuals with stereo televisions; and the feasibility of alternative methods of distribution, including cablecast open descriptions, broadcast descriptions inserted within the vertical blanking interval, simulcast descriptions, and the Second Audio Programming channel (SAP).

Research resulting from these projects would make major contributions to the body of knowledge regarding video description, would produce findings regarding the impact and relative effectiveness of various distribution methods, and may provide alternative technologies for broadcast distribution.

Priority: To be considered for funding under this priority, a project must—

(1) Address all of the issues identified in the background to this priority, and may also address any related issues;

(2) Identify specific strategies that would be used in the investigation;

(3) Carry out the research within a conceptual framework, based on previous research or theory, that provides a basis for the strategies to be studied, the research design, and target population;

(4) Collect, analyze, and report (a) a variety of descriptive and demographic data, including information regarding the potential target population, settings, and the service providers; and (b) outcome data on the effects of different distribution methods on the provision of video description services;

(5) Conduct the research using methodological procedures that would (a) produce unambiguous findings regarding the effects of the identified issues and alternative approaches; and (b) permit use of the findings in policy analyses; and

(6) Design the research activities in a manner that would lead to improved video-described services for individuals with visual impairments.

Absolute Priority 5—Research on Captioning as a Language Development Tool

Background: This priority supports research projects on the effectiveness of captioning as a language development tool for enhancing the reading and literacy skills of individuals who are deaf or hard of hearing, as well as the reading and literacy skills of individuals with other disabilities. Issues to be explored by projects funded under this priority could include, but are not limited to (1) captioning styles currently being developed or studied; (2) captioning features as effective educational tools; and (3) the use of captions with other media and multi-media technologies such as interactive videodiscs and CD–ROMs.

Priority: To be considered for funding under this priority, a project must—

(1) Address any of the issues identified in the background to this priority or closely related issues;

(2) Identify specific technological approaches that would be investigated;

(3) Carry out the research within a conceptual framework, based on previous research or theory, that provides a basis for the strategies to be studied, the research design, and target population;

(4) Collect, analyze and report (a) characteristics and outcomes data, including the settings, the service providers, and the individuals targeted by the project (e.g., age, disability, level of functioning, membership in a special population, if appropriate); and (b) multiple, functional outcome data on the individuals who are the focus of the technological approaches;

(5) Conduct the research in settings such as residential or integrated schools or colleges, or in community settings, as appropriate;

(6) Conduct the research using methodological procedures that would (a) produce unambiguous findings regarding the effects of the approaches and interaction effects between particular approaches and particular groups of individuals or particular settings; and (b) permit use of the findings in policy analyses; and

(7) Design the research activities in a manner that would lead to improved services for individuals with hearing impairments or with other disabilities, as may apply.

Absolute Priority 6—Symposium on Exploring New Strategies for Providing Captioned Media Services

Background: This priority supports one cooperative agreement for a three-day symposium to determine the best strategy or strategies for expanding the availability of captioned media, including captioned videos and closed-captioned television programs, to deaf and hard of hearing individuals in various educational and non-educational settings.

The Captioned Films Loan Service for the Deaf Program (CFD) was created in 1958 by Public Law 85–905 with the original purpose of giving people who are deaf access to motion pictures and enhancing the cultural, educational, and general welfare of that population. At that time most students who are deaf were educated at residential schools. Therefore, when CFD expanded to include the distribution of captioned educational films to students who are deaf, film depositories were established on, though not limited to, some of those campuses.

The depository system has changed little since that time, although deaf and hard of hearing students are now educated primarily in more integrated and local settings. The Secretary is particularly interested in seeking more effective means of providing educational media services to this population while continuing to serve students in residential settings.

During the 1970's closed-captioned television was included among CFD's projects. In 1972 a contract was awarded to develop and test Line 21 concepts and, eventually, prototype decoders. Closed-captioned television, which was entirely supported with Federal funds, officially began in 1980, and the first real-time closed-captioned broadcast took place in October 1982. The number of captioning hours of prime time television started with 16 hours in 1981. Currently all prime time programming, all Saturday morning children's programs, and many daytime and late night programs are closed captioned.

Closed-captioned television is an example of cooperative efforts between the public and private sectors. Department of Education funding provides approximately 40 percent of the current captioning available. The networks currently provide approximately 30 percent, and corporate advertisers, foundations, and contributions account for the remaining 30 percent. Meanwhile, there has been a significant increase in the number of programs being captioned. Further, the Television Decoder Circuitry Act of 1990 mandates that, after July 1993, all television sets with screens 13 inches and larger manufactured in the United States or imported for use in the United States must have built-in circuitry designed to display closed captioning. This Act, along with the increase in the number of available captioned programs, the increase in the number of private funding sources, and the expanded array of television programming options combine to make it necessary to consider the most effective ways to ensure full access to expanded captioned programs in the future.

Thus, the symposium aims to explore strategies that the Department may consider making captioned videos available to a wider number of deaf and hard of hearing individuals, especially those attending local or mainstreamed schools, and strategies for expanding captioned television programming in light of future technology that will increase the number of available channels to 500.

Priority: To be considered for funding under this priority, the project must—

(1) Conduct pre-symposium activities, including reviewing reports and recommendations that resulted from previous evaluation studies of the Captioned Films Program, closed-captioned television, and related materials;

(2) Conduct a symposium that offers at least six work sessions, led by professionals or experts in areas including, but not limited to (a) educational media and technology, (b) television captioning technology, (c) special education administration, covering both mainstream and residential programs, (d) media distribution, (e) consumer advocacy, and (f) film and television post-production services;

(3) Make arrangements for participants to discuss and respond to issues and strategies that would be raised at the symposium—particularly strategies for improving services for deaf and hard of hearing consumers;

(4) Conduct post-symposium activities, including refining formally presented papers, reflecting group discussions and concerns expressed at the symposium, as well as potential strategies and directions for improved services i.e., for better delivery of captioned videos and expanding the availability of closed-captioned television programming; and

(5) Publish a proceedings document and distribute this document to symposium participants and relevant clearinghouses and organizations.

Absolute Priority 7—Educational Video Selection and Captioning

Background: This priority supports one cooperative agreement that will screen, evaluate, caption, and make available educational videos, including classics and special interest titles, for use by students and other individuals who are deaf or hard of hearing, parents of deaf and hard of hearing individuals, and other individuals directly involved in activities promoting the advancement of deaf and hard of hearing individuals in the United States. This activity includes the preparation of captions on computer diskettes. This priority will ensure that students and other individuals with hearing impairments benefit from the same educational videos used to enrich the educational experiences of students and other individuals without hearing impairments.

Priority: To be considered for funding under this priority, the project must—

(1) Develop strategies and procedures to be used in determining curricular needs of deaf and hard of hearing

students in all types of school settings for captioned videos;

(2) Develop and implement an on-going evaluation program for incorporating the reaction and suggestions of users into the selection and captioning process;

(3) Establish liaison with and obtain videos from film and video distributors for viewing and evaluation. Select from among submitted video titles those that closely match the curricular needs identified under paragraph (1) of this proposed priority, taking into account the videos most commonly used in school districts across the Nation for all students;

(4) Develop and implement criteria and procedures for screening and evaluating selected titles;

(5) Make arrangements with respective producers and distributors to have selected videos captioned and made available through general distribution mechanisms (such as video sales catalogues), as well as through the captioned film and video loan service authorized under part F of IDEA and 34 CFR part 330 (by purchasing up to 100 copies of each captioned title, some which will be open-captioned and some which will be closed-captioned);

(6) For selected titles, prepare captions on computer diskettes and check for accuracy. These captions would take into account the age and reading levels of the likely target audience;

(7) Identify, select, and, if necessary, provide training to video evaluators and caption checkers;

(8) Develop and implement quality control guidelines and procedures for checking videocassettes after they are captioned; and

(9) Prepare and make available to potential consumers information about the availability of captioned videos, including information about the captioned film and video loan service, regulations governing the use of captioned films and videos in the collection, procedures for applying for these services, and descriptions of the videos available.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Applicable Program Regulations: 34 CFR parts 330, 331, and 332 Program Authority: 20 U.S.C. 1451, 1452.

Dated: October 15, 1993.

Andrew Pepin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

(Catalogue of Federal Domestic Assistance Number: 84.026, Educational Media Research, Production, Distribution, and Training Program)

[FR Doc. 93–25810 Filed 10–20–93; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No.: 84.026]

Educational Media Research, Production, Distribution, and Training Program; Inviting Application for New Awards for Fiscal Year (FY) 1994

Purpose of Program: The purposes of this program are to promote the general welfare of deaf, hard-of-hearing, and visually impaired individuals, and the educational advancement of individuals with disabilities.

These priorities support the National Educational Goals by assisting those with disabilities in meeting Goal 1, school readiness, and Goal 5, adult literacy.

Eligible Applicants: Profit and nonprofit public and private agencies, organizations, and institutions are eligible to apply for a grant.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85 and 86; and (b) The regulations for this program in 34 CFR part 332.

Priorities: The priorities in the notice of final priorities for this program as published elsewhere in this issue of the **Federal Register**, apply to these competitions.

Applications Available: October 26, 1993.

EDUCATIONAL MEDIA RESEARCH, PRODUCTION, DISTRIBUTION, AND TRAINING

Title and CFDA No.	Deadline for transmittal of applications	Deadline for intergovernmental review	Available funds	Estimated range of awards	Estimated size of awards	Estimated number of awards	Project period in months
Closed-Captioned Sports Program (CFDA 84.026A).	2/04/94	4/05/94	$750,000	$250,000–750,000	$250,000	1 to 3	Up to 36.
Broadcast and Cable Television Description (CFDA 84.026C).	2/03/94	4/04/94	$500,000	$250,000–500,000	$250,000	1 to 2	Up to 36.
Described Home Video (CFDA 84.026H).	3/03/94	5/02/94	$250,000	$225,000–250,000	$250,000	1	Up to 36.
Research on Video Description (CFDA 84.026G).	2/04/94	4/05/94	$250,000	$50,000–250,000	$62,500	1 to 4	Up to 24.
Research on Captioning as a Language Development Tool (CFDA 84.026R).	2/04/94	4/05/94	$400,000	$75,000–100,000	$100,000	4	Up to 24.
Symposium on Exploring New Strategies (CFDA 84.026M).	2/04/04	4/05/94	$150,000	$125,000–150,000	$150,000	1	Up to 18.
Educational Video Selection and Captioning (CFDA 84.026D).	1/03/94	3/04/94	$700,000	$650,000–700,000	$700,000	1	Up to 36.

Note: The Department is not bound by any estimates in this notice.

For Applications: To request an application, telephone (202) 205–8485. Individuals who use a telecommunications device for the deaf (TDD) may call (202) 205–8169.

For Further Information Contact: Ernest E. Hairston, U.S. Department of Education, 400 Maryland Avenue, SW., room 4629, Switzer Building, Washington, DC 20202–2644. Telephone: (202) 205–9172. Individuals who use a telecommunications device for the deaf (TDD) may call (202) 205–8169.

Program Authority: 20 U.S.C. 1451, 1452.

Dated: October 15, 1993.

Andrew Pepin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 93–25811 Filed 10–20–93; 8:45 am]

BILLING CODE 4000–01–P

federal register

Thursday
October 21, 1993

Part IV

Department of Labor

Pension and Welfare Benefits Administration

29 CFR Part 2530
Qualified Domestic Relations Orders; Request for Information

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2530

Qualified Domestic Relations Orders

AGENCY: Pension and Welfare Benefits Administration.

ACTION: Request for information.

SUMMARY: This document is a request for information to assist the Department of Labor (the Department) in assessing the need for a regulation clarifying certain statutory requirements set forth in Title I of the Employee Retirement Income Security Act (ERISA) and in the Internal Revenue Code (the Code) with regard to qualified domestic relations orders (QDROs). Under provisions creating a limited exception to the anti-assignment and alienation provisions of ERISA and the Code and to the preemption provision of ERISA (hereinafter collectively the QDRO provisions), benefits under a pension plan may be assigned or alienated pursuant to an order issued under state domestic relations law if the order constitutes a qualified domestic relations order. The QDRO provisions generally specify the circumstances under which plan administrators and other plan fiduciaries are required to give effect to a QDRO.

The Department anticipates that information and views provided by plan sponsors, plan fiduciaries, service providers to plans, plan participants and beneficiaries, and other interested persons will aid it in assessing the need for issuing a regulation under the QDRO provisions and the appropriate scope and content of any such regulation. The Department also anticipates that a regulation under the QDRO provisions may have some impact on the interpretation of ERISA's provisions relating to qualified medical child support orders, which were enacted as part of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). A regulation on the QDRO provisions would affect participants and beneficiaries (including alternate payees) of certain pension benefit plans, as well as the sponsors and fiduciaries of such plans.

DATES: Written comments should be received by the Department of Labor on or before December 20, 1993.

ADDRESSES: Comments (preferably, at least six copies) should be addressed to the Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, room N–5669, U.S. Department of Labor, Washington, DC 20210. Attention: QDRO RFI. All comments received will be available for public inspection at the Public Disclosure Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, room N–5507, 200 Constitution Ave., NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Deborah Hobbs, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor, Washington, DC 20210, telephone (202) 219–7901; or Susan Rees, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, Washington, DC 20210, telephone (202) 219–9141. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

A. General

1. Qualified Domestic Relations Order Provisions

Section 206(d)(3) of Title I of ERISA, and the related provisions of section 414(p) of the Code,[1] establish a limited exception to the prohibitions against assignment and alienation contained in ERISA section 206(d)(1) and Code section 401(a)(13).[2] Under this limited exception, a participant's benefits under a pension plan may be assigned or alienated pursuant to an order that constitutes a qualified domestic relations order (QDRO) within the meaning of those provisions.[3] Such QDROs, in addition, survive the federal preemption of State law imposed by ERISA section 514(a) by virtue of ERISA section 514(b)(7), which provides that section 514(a) "shall not apply to qualified domestic relations orders (within the meaning of section 206(d)(3)(B)(i))."

Pursuant to the QDRO provisions, a plan administrator must determine, in accordance with specified procedures, whether an order purporting to divide a participant's benefits under a plan meets the applicable requirements set forth in section 206(d)(3) of ERISA. If the plan administrator determines that the order meets these requirements and is, accordingly, a QDRO within the meaning of section 206(d)(3), the plan administrator must distribute the assigned portion of the participant's benefits to the alternate payee or payees[4] named in the order in accordance with the terms of the order. An alternate payee named in a QDRO must be treated as a beneficiary under the plan pursuant to section 206(d)(3)(J).[5]

Subparagraphs (G) and (H) of ERISA section 206(d)(3) set forth provisions relating to the procedures that a plan must establish, and a plan administrator must observe, in determining whether an order is a qualified domestic relations order, and in administering the plan and the participant's benefits during the period in which the plan administrator is making such a determination. The plan's procedures must be reasonable, must be in writing, must require prompt notification and disclosure of the procedures to participants and alternate payees upon receipt of an order, and must permit alternate payees to designate representatives for notice purposes. In addition, the plan administrator must complete the determination process and notify participants and alternate payees of its determination within a reasonable period after receipt of the order.[6]

Subparagraph (H) of section 206(d)(3) provides specific procedural protection

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[1] All references herein to ERISA section 206(d)(1) should be read to refer also to Code section 401(a)(13). Similarly, except where no corresponding provision exists, all references to paragraphs of ERISA section 206(d)(3) should be read to refer also to the corresponding provisions of Code section 414(p).

[2] The QDRO provisions were added to ERISA and the Code by the Retirement Equity Act of 1984 (REA), Public Law No. 98–397, 98 Stat. 1426 (1984). Section 302(a) of REA provided that, except as otherwise provided in sections 302 or 303, the amendments made by REA were applicable to plan years beginning after December 31, 1984. REA, Public Law No. 98–397, sections 302, 303, 98 Stat. 1426, 1451–1454. Amendments were made to the QDRO provisions by the Tax Reform Act of 1986, Public Law No. 99–514, section 1898, 100 Stat. 2085, 2957 (1986); by the Technical and Miscellaneous Revenue Act of 1988, Public Law No. 100–647, section 1018(t), 102 Stat. 3342, 3589 (1988); and by the Omnibus Budget Reconciliation Act of 1989, Public Law No. 101–239, section 7841(a), 103 Stat. 2106, 2427 (1989).

[3] The QDRO exception is applicable to pension plans that are subject to the prohibition against assignment and alienation contained in ERISA section 206(d)(1) and Code section 401(a)(13). ERISA section 206(d)(3)(L). See also Code sections 414(p) (9) and (11).

[4] Section 206(d)(3)(K) defines the term "alternate payee" to mean any spouse, former spouse, child or other dependent of a participant who is recognized by a domestic relations order as having a right to receive all, or a portion of, the benefits payable under a plan with respect to such participant.

The legislative history of this section indicates that a QDRO may, under certain circumstances, order that payment be made to an agent of the alternate payee. See Staff of Joint Committee on Taxation, 99th Cong., 2d Sess., Explanation of Technical Corrections to the Tax Reform Act of 1984 and Other Recent Tax Legislation 222 (Comm. Print 1187).

[5] The Code contains no provision parallel to ERISA section 206(d)(3)(J).

[6] The legislative history of REA specifically authorizes the Secretary of Labor to prescribe regulations defining what is a reasonable period for this purpose. See H.R. Rep. No. 655, 98th Cong., 2d Sess. 20 (1984); and S. Rep. No. 575, 98th Cong., 2d Sess. 22 (1984).

of a potential alternate payee's interest in a participant's benefits during the plan's determination process and for a period of up to 18 months (the 18-month period) during which the issue of the qualified status of a domestic relations order is being determined—whether by the plan administrator, by a court of competent jurisdiction, or otherwise. During the 18-month period, a plan administrator must separately account for any amounts that would have been payable to the alternate payee if the order had been immediately treated as a QDRO and must pay these amounts (including any interest thereon) to the alternate payee if the order is deemed qualified within such period. If the issue as to whether the order is a QDRO is not resolved within the 18-month period, the plan administrator is to pay such amounts to the person or persons who would have been entitled to the amounts if there had been no order. Any determination that an order is a QDRO which is made after the close of the 18-month period is to be applied prospectively only.[7]

In addition, there is evidence that Congress intended to permit plan administrators to take additional steps to protect an alternate payee's potential interest in plan benefits, where the plan administrator is on notice that rights to such benefits are in dispute. The Conference Committee Report on the Tax Reform Act of 1986, in discussing technical corrections to the QDRO provisions, states:

> [T]he committee intends that the plan administrator may delay payment of benefits for a reasonable period of time if the plan administrator receives notice that a domestic relations order is being sought. For example, a participant in a profit-sharing plan which is exempt from the survivor benefit rules requests a lump sum distribution from the plan. Before the distribution is made, the plan administrator receives notice that the participant's spouse is seeking a domestic relations order.
>
> The plan administrator may delay payment of benefits.

H.R. Conf. Rep. No. 841, 99th Cong., 2d Sess. II–858 (1986). See also Staff of Joint Committee on Taxation, 99th Cong., 2d Sess., Explanation of Technical Corrections to the Tax Reform Act of 1984 and Other Recent Tax Legislation 225 (Comm. Print 1187).[8]

If a plan fiduciary, acting in accordance with the fiduciary responsibility provisions of part 4 of title I of ERISA, treats an order as a QDRO (or determines that such an order is not qualified) and distributes benefits in accordance with that determination, paragraph (I) of section 206(d)(3) provides that the obligations of the plan and its fiduciaries to the affected participants and alternate payees with respect to the distribution shall be treated as discharged.[9]

The QDRO provisions detail specific requirements that an order must satisfy in order to constitute a QDRO.[10] The order must be a "domestic relations order" issued pursuant to a State domestic relations law (including a community property law) that relates to the provision of child support, alimony payments, or marital property rights to a spouse, former spouse, child or other dependent of a participant.[11] Section 206(d)(3)(B)(ii). It must create or recognize the existence of an alternate payee's right to receive all or a portion of the benefits payable to a participant under a plan. Section 206(d)(3)(B)(i). Further it must clearly specify the name and last known mailing address (if any) of the participant and the name and mailing address of each alternate payee covered by the order; the amount or percentage of the participant's benefits to be paid by the plan(s) to each such alternate payee, or the manner in which such amount or percentage is to be determined; the number of payments or period to which the order applies; and each plan to which the order applies. Section 206(d)(3)(C). An order will fail to qualify as a QDRO, however, if it requires the plan to provide any type or form of benefit, or any option, not otherwise provided under the plan; to provide increased benefits determined on the basis of actuarial value; or to pay benefits to an alternate payee that are required to be paid to another alternate payee under another order previously determined to be a qualified domestic relations order.[12] Section 206(d)(3)(D).

An order may provide for payments to an alternate payee before the participant has separated from service if such payments begin on or after the date on which the participant attains (or would have attained) his or her "earliest retirement age." Section 206(d)(3)(E). "Earliest retirement age" is defined as the earlier of (1) the date on which the participant is entitled to a distribution under the terms of the plan; or (2) the later of the date the participant attains age 50 or the earliest date on which the participant could begin receiving benefits under the plan.[13] Section 206(d)(3)(E)(ii).

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[7] In this regard, the legislative history of REA explains that, if the plan administrator determines that the order is qualified after the end of the 18-month period, the plan is not liable for payments to the alternate payee for the period before the order is determined to be qualified. The legislative history also indicates, however, that an alternate payee may have a cause of action under state law against the participant for any amounts paid to the participant that should have been paid to the alternate payee. See S. Rep. No. 575, 98th Cong., 2d Sess. 22 (1984); and H.R. Rep. No. 655, 98th Cong., 2d Sess. 21 (1984).

[8] The Joint Committee on Taxation further indicated that Congress intended to permit a plan administrator to honor a State court's restraining order, even if the order does not constitute a QDRO. The Joint Committee on Taxation stated: "Notice of issuance of a stay during the time an appeal is pending is deemed to be notice that the parties are attempting to cure deficiencies in a domestic relations order. Further, the Congress intends that a plan administrator will honor a restraining order prohibiting the disposition of a participant's benefits pending resolution of a dispute with respect to a domestic relations order."

Staff of Joint Committee on Taxation, 99th Cong., 2d Sess., Explanation of Technical Corrections to the Tax Reform Act of 1984 and Other Recent Tax Legislation 224–25 (Comm. Print 1187).

[9] There is no parallel provision in section 414(p) of the Code. Code section 414(p)(10) provides, however, that, with respect to the requirements of subsections (a) and (k) of section 401, section 403(b), and section 409(d), a plan shall not be treated as failing to meet such requirements solely by reason of payments made to an alternate payee pursuant to a QDRO.

[10] The Department has taken the position, pursuant to section 5 of ERISA Procedure 76–1, that it will not ordinarily issue advisory opinions addressing whether a particular order constitutes a qualified domestic relations order under section 206(d)(3) because such a determination requires resolution of a number of factual issues, as well as the interpretation and application of the provisions of the plan(s) to which the order applies. The issuance of this Request for Information does not reflect any change in the Department's views on this issue.

[11] In Advisory Opinion 90–46A, dated December 4, 1990, the Department concluded the term "domestic relations order" as used in section 206(d)(3)(B)(ii) did not include a state probate court's order recognizing, on the basis of state community property law, an estate's interest in the pension benefits of the deceased's surviving spouse. The Department noted that Congress intended that the QDRO provisions would have application in those court proceedings conducted primarily to resolve domestic relations issues and would not be available to serve as a mechanism by which a non-participant spouse's interest derived only from state community property law could be enforced against a pension plan.

[12] The legislative history of the QDRO provisions provides guidance concerning the manner in which benefits may be divided pursuant to a QDRO. It is indicated, for example, that a QDRO may, but is not required to, provide that an alternate payee's portion of a participant's benefits shall increase if the participant's total accrued benefits increase. See H.R. Rep. No. 655, 98th Cong., 2d Sess. 20 (1984). A QDRO may also, but is not required to, provide the alternate payee with a portion of any subsidy to which the participant may become entitled. See S. Rep. No. 575, 98th Cong., 2d Sess. 21 (1984). See also S. Rep. No. 575, 98th Cong., 2d Sess. 21 (1984) (stating general rule that payments to an alternate payee made before the participant retires should be calculated based only on benefits actually accrued and not taking into account any subsidy to which the participant might become entitled); 130 Cong. Rec. 23486–23487 (1984) (floor debate setting out examples of permissible methods of calculating an alternate payee's share and demonstrating how the prohibition against increased benefits should operate).

[13] The Conference Committee Report on the Tax Reform Act of 1986, discussing this provision, explains: "For example, in the case of a plan which provides for payment of benefits upon separation

Continued

A QDRO may provide that the former spouse of a participant shall be treated as a surviving spouse for purposes of section 205 of ERISA. To the extent that a QDRO so provides, the current spouse of the participant shall not be treated as the participant's surviving spouse for those purposes.[14] Section 206(d)(3)(F).

2. Qualified Medical Child Support Order Provisions

The Omnibus Budget Reconciliation Act of 1993 (OBRA '93) amended Part 6 of subtitle B of title I of ERISA to add a new section 609 that provides, in part, that group health plans must provide benefits with respect to a child of a participant in accordance with the applicable requirements of any qualified medical child support order (QMCSO) (hereinafter collectively the QMCSO provisions).[15] OBRA '93 also amended ERISA section 514 to provide, *inter alia*, that an order that is a QMCSO within the meaning of section 609(a)(2)(A) shall survive the preemption of state law imposed by that section.[16] The Department notes that section 609(e) grants the Secretary of Labor authority to issue regulations under section 609 of ERISA in consultation with the Secretary of Health and Human Services.

The QMCSO provisions of ERISA section 609(a) were modelled in large part on the QDRO provisions and, therefore, contain many similar requirements. For example, section 609(a)(5) imposes procedural requirements on the administrator of a group health plan with respect to any medical child support order received by the plan that are substantially similar to the procedural requirements that a pension plan administrator must follow in determining whether a domestic relations order constitutes a QDRO. Because of the similarities between the QDRO provisions and the QMCSO provisions and the resulting likelihood that regulations under the QDRO provisions would affect the interpretation of the QMCSO provisions, the Department asks that commentators consider these similarities in formulating comments on the QDRO provisions.

B. Comments

As described herein, the QDRO provisions impose numerous obligations on a variety of parties. The QDRO provisions establish procedures and provide roles for participants, persons seeking the status of alternate payee, State courts adjudicating domestic relations laws, Federal courts acting under ERISA, and plan administrators. The Department, in assessing the need for administrative rulemaking in this area, is interested in information from the public on the problems, if any, that have arisen in interpreting the QDRO provisions.[17] The Department invites interested parties to submit comments that pertain to any such problems. The Department further invites interested parties to submit their views on the extent to which such problems could be resolved through the issuance of regulatory guidance.

In order to assist interested parties in responding, this Notice describes specific areas in which the Department is particularly interested. The Department, however, also requests comments and suggestions concerning any other problems or issues pertinent to the Department's assessment of the possible need for regulatory guidance in this area. It is requested that the public, in responding to specific questions proposed by this Notice, refer to the question number listed in this Notice. Reference to the appropriate question number will aid the Department in analyzing submissions.

Specific areas with respect to which the Department is interested include:

1. Whether problems have arisen relating to whether, and to what extent, state or federal law applies to issues arising under the QDRO provisions.

2. Whether fiduciary or other problems have arisen relating to the plan administrator's various duties under the QDRO provisions, including providing information to participants and potential alternate payees, determining whether an order constitutes a QDRO, making such a determination within a "reasonable period" after receipt of the order, protecting the plan from adverse consequences (including double payment to participants and alternate payees), and administering plan benefits that have been divided pursuant to a QDRO.

3. Whether problems have arisen relating to interpretation of the particular requirements and limitations enumerated in ERISA section 206(d)(3) with respect to the qualified status of a domestic relations order.

4. Whether problems have arisen relating to the procedural requirements established by subparagraphs (G) and (H) of section 206(d)(3) for the process by which a plan administrator must determine whether a proposed order is a qualified domestic relations order, and for the interim administration of the plan and the participant's benefits during the period in which the plan administrator is making such a determination.

5. Whether problems have arisen in determining whether rights and benefits granted to an alternate payee pursuant to a QDRO, or pursuant to a plan's provisions, or both, are consistent with Title I of ERISA and the applicable provisions of the Code.

All submitted comments will be made a part of the record of the proceeding referred to herein and will be available for public inspection.

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from service (but not before then), the earliest date on which a QDRO can require payments to an alternate payee to begin is the date the participant separates from service. A QDRO could also require such a plan to begin payments to an alternate payee when the participant attains age 50, even if the participant has not then separated from service."

H.R. Conf. Rep. No. 841, 99th Cong. 2d Sess. II–858 (1986).

[14] The legislative history of the QDRO provisions discusses the effect of a QDRO's treating a former spouse as the surviving spouse. See S. Rep. No. 575, 98th Cong., 2d Sess. 20 (1984) (indicating that, to the extent that a QDRO provides that a participant's current spouse shall not be treated as his spouse under the plan with respect to benefits awarded to an alternate payee, the participant's current spouse would have no spousal rights under ERISA section 205); 130 Cong. Rec. 23486–23487 (1984) (floor debate asserting that if a former spouse is named as alternate payee, the qualified joint and survivor annuity (QJSA) and qualified preretirement survivor annuity (QPSA) protections of ERISA section 205 shall not apply to the benefits awarded to the alternate payee, except to the extent consistent with the QDRO); H.R. Rep. No. 655, 98th Cong., 2d Sess. 19–20 (1984); and S. Rep. No. 575, 98th Cong., 2d Sess. 21 (1984) (stating that, if a former spouse is named by a QDRO as an alternate payee, but the participant dies before attaining earliest retirement age under the plan and before the alternate payee receives payment of the assigned portion of the participant's benefits, the alternate payee shall be entitled to survivor benefits only to the extent that the QDRO specifically requires survivor benefits to be paid).

[15] ERISA section 609, added by OBRA '93, Public Law No. 103–66, section 4301(a) (1993). Section 609(a) relates to QMCSOs.

[16] OBRA '93, Public Law No. 103–66, section 4301(c)(4) (1993) (amending ERISA section 514(b)(7)).

[17] Pursuant to section 206(d)(3)(N) of ERISA and section 414(p)(12) of the Code, the Secretary of Labor has the authority to promulgate regulations under section 206(d)(3) of ERISA and section 414(p) of the Code after consultation with the Secretary of the Treasury.

Pursuant to section 401(n) of the Code, the Secretary of the Treasury also has authority to prescribe rules or regulations as may be necessary to coordinate the requirements of Code section 401(a)(13)(B) and Code section 414(p) (and any regulations issued by the Secretary of Labor thereunder) with the other provisions of Chapter 1 of Subtitle A of the Code. The Treasury Department has promulgated certain regulations relating to distributions pursuant to a QDRO. See Treas. Reg. §§ 1.401(a)–13(g); 1.401(a)–20, Q&A 10, Q&A 25(b), Q&A 27, Q&A 28, and Q&A 31; See also Prop. Treas. Reg. §§ 1.401(a)(9)–1, Q&A H–4; 1.401(a)(9)–2, Q&A 7 and Q&A 11.

Signed at Washington, DC this 15th day of October 1993.

Olena Berg,

Assistant Secretary for Pension and Welfare Benefits, U.S. Department of Labor.

[FR Doc. 93–25908 Filed 10–20–93; 8:45 am]

BILLING CODE 4510–29–M

federal register

Thursday
October 21, 1993

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310

Digestive Aid Drug Products for Over-the-Counter Human Use; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 81N–0106]

RIN 0905–AA06

Digestive Aid Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that activated charcoal and certain other digestive aid ingredients for over-the-counter (OTC) human use are not generally recognized as safe and effective and are misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on OTC digestive aid drug products that have come to the agency's attention. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: April 21, 1994.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 1982 (47 FR 454), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC digestive aid drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by April 5, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by May 5, 1982.

In a document that published in the **Federal Register** on March 30, 1982 (47 FR 13385), the agency advised that it had extended the comment period until June 4, 1982, and the reply comment period to July 5, 1982, on the advance notice of proposed rulemaking for OTC digestive aid drug products to allow for consideration of additional data and information.

In accordance with § 330.10(a)(10), the data and information considered by the Panel, after deletion of a small amount of trade secret information, were placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC digestive aid drug products was published in the **Federal Register** of January 29, 1988 (53 FR 2706). Interested persons were invited to file by March 29, 1988, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by May 31, 1988. New data could have been submitted until January 30, 1989, and comments on the new data until March 29, 1989.

In a document that published in the **Federal Register** on April 19, 1988 (53 FR 12779), the agency advised that it had extended the comment period until May 27, 1988, to allow adequate time for one manufacturer to fully evaluate information it had recently received from the agency and to prepare comments to the notice of proposed rulemaking.

In the **Federal Register** of November 7, 1990 (55 FR 46914), the agency published a final rule establishing that certain active ingredients that had been under consideration in a number of OTC drug rulemaking proceedings were not generally recognized as safe and effective. That final rule was effective on May 7, 1991, and included in § 310.545(a)(8) (21 CFR 310.545(a)(8)) 21 ingredients that had been under consideration as part of this rulemaking for OTC digestive aid drug products.

In the **Federal Register** of May 10, 1993 (58 FR 27636), the agency published a final rule establishing that certain additional active ingredients that had been under consideration in a number of OTC drug rulemaking proceedings were not generally recognized as safe and effective. That final rule is effective on November 10, 1993, and included in § 310.545(a)(8)(ii) 83 additional ingredients that had been under consideration as part of this rulemaking for OTC digestive aid drug products.

After these two final rules were published, only two ingredients remained to be evaluated in this rulemaking: Activated charcoal and lactase enzyme. The agency's action in this document completes the OTC digestive aids rulemaking with respect to activated charcoal. In this final rule, the agency is adding new paragraph (a)(8)(iii) to § 310.545 to establish that activated charcoal is not generally recognized as safe and effective and is misbranded when present in OTC digestive aid drug products. The agency will publish its final decision on the status of lactase enzyme in OTC digestive aid drug products in a future issue of the **Federal Register.**

The agency stated in the tentative final monograph (53 FR 2706 at 2709) that at that time no submissions had been made to the agency regarding lactase enzyme products, nor was the agency aware of any specific data that would establish general recognition of safety and effectiveness for this ingredient. The agency acknowledged that lactase enzyme is contained in a number of marketed products and is promoted for use as a digestive aid for persons who are intolerant to lactose-containing foods. Although lactase deficiency can be controlled by ingestion of a lactose-free diet, the agency stated that lactase enzyme products could be potentially useful for those persons who do not wish to avoid lactose in their diets. Therefore, the agency invited interested persons to submit specific data and information regarding the use of lactase enzyme products.

In response to the proposed rule, two manufacturers submitted the results of several new studies to demonstrate the effectiveness of lactase enzyme derived from *Aspergillus oryzae* and *A. niger.* The agency is currently reviewing these studies and is awaiting additional information from both manufacturers. Accordingly, in order to complete this rulemaking with regard to all other conditions except lactase enzyme, the agency is not addressing the data submitted on lactase enzyme at this time. Those data will be addressed as soon as the agency's review is completed. If the data support the safety and effectiveness of lactase enzyme, the agency will propose to establish a monograph for OTC digestive aid drug products at that time. Appropriate labeling will be proposed based on the results of the studies being evaluated. In the interim, products containing lactase enzyme may remain in the marketplace and are not subject to this final rule.

In the tentative final monograph for OTC digestive aid drug products (53 FR 2706), the agency did not propose any active ingredient as generally recognized as safe and effective and not misbranded. However, the agency proposed monograph labeling in the

event that data were submitted that resulted in the upgrading of any ingredient to monograph status. In this final rule, no active ingredient has been determined to be generally recognized as safe and effective for use in OTC digestive aid drug products. As noted above, the monograph status of lactase enzyme is still under evaluation. Therefore, proposed subpart D of part 357 (21 CFR part 357) for OTC digestive aid drug products is being held in abeyance until the agency's review of lactase enzyme is completed.

This final rule declares OTC digestive aid drug products containing the active ingredient activated charcoal to be new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321(p)), for which an application or abbreviated application (hereinafter called application) approved under section 505 of the Act (21 U.S.C. 355) and 21 CFR part 314 is required for marketing. In the absence of an approved application, products containing activated charcoal for this use also would be misbranded under section 502 of the Act (21 U.S.C. 352). In appropriate circumstances, a citizen petition to establish a monograph may be submitted under § 10.30 (21 CFR 10.30) in lieu of an application.

The OTC drug procedural regulations (§ 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA does not use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term "monograph conditions" is used; in place of Categories II or III, the term "nonmonograph conditions" is used.

In the proposed rule for OTC digestive aid drug products (53 FR 2706), the agency advised that it would provide a period of 12 months after the date of publication of the final monograph in the **Federal Register** for relabeling and reformulation of digestive aid drug products to be in compliance with the monograph. Although data and information were submitted on activated charcoal in response to the proposed rule, they were not sufficient to support monograph conditions, and no monograph is being established at this time. Therefore, digestive aid drug products that are subject to this rule are not generally recognized as safe and effective and are misbranded (nonmonograph conditions). In the advance notice of proposed rulemaking (47 FR 454 at 455), the agency advised that conditions for OTC digestive aid drug products that are not generally recognized as safe and effective and are misbranded would be effective 6 months after the date of publication of a final rule in the **Federal Register**. Because no OTC drug monograph is being established for this class of drug products, the agency is adopting this 6-month effective date for the nonmonograph conditions in this final rule. This 6-month effective date is also consistent with the effective dates for the other digestive aid active ingredients included in § 310.545(a)(8). Therefore, on or after April 21, 1994, no OTC drug products that are subject to this final rule may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved application.

In response to the proposed rule on OTC digestive aid drug products, two drug manufacturers and three physicians submitted comments on activated charcoal, and four drug manufacturers submitted comments on lactase enzyme. A request for an oral hearing before the Commissioner of Food and Drugs was received on one issue. Copies of the comments and the hearing request received are on public display in the Dockets Management Branch (address above). Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

The hearing request is discussed in comment 1. (see section I.A. of this document). In proceeding with this final rule, the agency has considered all objections, requests for oral hearing, and the changes in the procedural regulations. A summary of the comments and the new data with FDA's responses to them follows.

I. The Agency's Conclusions on the Comments

A. Comments on Activated Charcoal

1. Two comments submitted data (Refs. 1 through 6) to support the use of activated charcoal for the treatment of intestinal distress related to gas. The comments requested that activated charcoal be included in either the monograph for OTC antiflatulent or OTC digestive aid drug products. One comment requested an oral hearing regarding inclusion of activated charcoal in the OTC antiflatulent monograph if it was found to be a Category I ingredient in the OTC digestive aid monograph. Two other comments argued that activated charcoal was an antiflatulent ingredient and objected to its inclusion in the OTC digestive aid monograph.

The agency has reviewed the data and concludes that they are insufficient to support the use of activated charcoal for the treatment of intestinal distress related to gas. Accordingly, activated charcoal will not be included in either monograph, and a hearing is not necessary.

Jain et al. (Ref. 1) conducted a randomized, placebo-controlled, double-blind, crossover study in which the effect of activated charcoal in reducing gas in the lower intestinal tract was evaluated by measuring breath hydrogen levels. Sixty-nine healthy adults in India and 30 in the United States participated in the study. Serial end-expiratory breath samples were collected at 30-minute intervals from each subject for 4½ hours. A dose of 1,040 milligrams (mg) of activated charcoal or placebo was administered after the first sample was collected and again 1 hour later. Lactulose, the substrate used to produce hydrogen in the colon, was administered ½ hour after the first dose. Symptoms of bloating, abdominal cramps, and diarrhea were recorded for 4 hours. The investigators reported that activated charcoal compared to placebo significantly ($p < 0.05$) reduced breath hydrogen levels and provided symptomatic relief (reduced symptoms of bloating, abdominal cramps, and diarrhea). One design problem with this study was that activated charcoal was given before the lactulose (the substance used to produce the hydrogen).

In a triple-crossover, double-blind, placebo-controlled study (Ref. 2), Jain et al. evaluated the effects of activated charcoal, placebo, and simethicone in reducing gas in the colon as measured by breath hydrogen levels in 10 healthy subjects. Results were provided for nine subjects; one subject was excluded due to failure to produce hydrogen gas. The study design was similar to that used in the first Jain et al. study (Ref. 1), except that 8 ounces (oz) of baked beans were used as the gas-producing substrate and serial breath samples were collected at 30-minute intervals for 7 hours. The beans were eaten 30 minutes after the first doses of either activated charcoal, simethicone, or placebo. Simethicone was administered at a dose of 80 mg and

activated charcoal at 1,040 mg, with repeat doses given after 1 hour. The investigators reported that only activated charcoal significantly ($p < 0.05$) reduced breath hydrogen levels and reduced abdominal symptoms (bloating and abdominal discomfort).

In a placebo-controlled, crossover study (Ref. 3), Vargo, Ozick, and Floch evaluated the effect of activated charcoal on breath hydrogen levels in 12 subjects after a bean meal using a design and dosage similar to the Jain studies. A statistically significant reduction ($p < 0.05$) in breath hydrogen levels was found only at the 7-hour (420-minute) collection period. Further, this study only measured breath hydrogen; symptoms of gas were not evaluated.

Hall, Thompson, and Strother (Ref. 4) evaluated the effects of activated charcoal on breath hydrogen levels and the number of flatus events in a randomized, double-blind, placebo-controlled, crossover study. Baseline data were collected on the number of times flatus was passed each hour for 7 hours following administration of a normal meal (containing no known gas-forming items). Each of the 13 subjects in this part of the study also had a bean meal on two separate occasions (with a period of at least 2 days between bean meals) and recorded flatus events after each bean meal. The subjects received either 582 mg of activated charcoal or placebo administered immediately after the bean meal and 2 hours later. In an additional test to determine the effectiveness of a smaller dose, seven subjects were given 388 mg of activated charcoal only at 2 hours after the meal. In the breath hydrogen portion of the study, 10 subjects were fed a normal meal and 10 subjects were fed a bean meal. The subjects fed the normal meal were not treated. The subjects receiving the bean meal were treated with either 582 mg of activated charcoal or placebo immediately after the meal and every 30 minutes thereafter for a total of five doses (2,910 mg of activated charcoal).

The mean number of flatus events per subject was almost three following the normal meal and 14.5 following the bean meal. When the bean meal was followed by activated charcoal, the mean number of flatus events decreased to less than three ($p < 0.001$ compared to placebo). In the additional study involving 388 mg of activated charcoal, the mean number of flatus events during the first 3 hours after the meal was greater compared to the subjects who received 582 mg. However, there was no significant difference between the two groups in the number of flatus events during the last 4 hours of observation. The authors explained this lack of difference on normal transit time to the colon (2 to 3 hours) and stated that once activated charcoal reaches the colon, the lower dose is also effective in reducing flatus events. In the breath hydrogen portion of the study, the mean breath hydrogen concentrations were similar for 4 hours following the normal meal and the bean meal followed by placebo. Thereafter, the concentrations increased threefold for the next 4 hours. Concentrations following the bean meal and activated charcoal remained low throughout the study and after the 4th hour were significantly different ($p < 0.001$) compared to the bean meal-placebo group.

In another study (Ref. 5), Potter et al. used in vitro and in vivo methods to evaluate the ability of activated charcoal to reduce intestinal gas production. The in vivo evaluation involved a double-blind study that measured breath hydrogen levels and flatus events of 10 healthy subjects. Each subject was studied on four occasions, twice with placebo and twice with activated charcoal. Subjects were fed a bean meal followed by 1,000 mg of activated charcoal or placebo. Doses were repeated every 30 minutes for a total of four doses. Breath hydrogen levels were obtained at time zero and every hour for 9 hours. Subjects also recorded the number of times they passed flatus. The investigators reported no significant differences in breath hydrogen levels or the number of flatus events between the treatment and placebo groups. The investigators concluded that activated charcoal does not reduce the volume of bowel gas.

Riggs (Ref. 6) reported the results of a study involving a pretest and test meal. Fifty-three subjects ate a gas-producing pretest meal and took two placebo capsules upon onset of symptoms. Subjects were dropped from the study if they did not develop symptoms within 1 hour or if they developed symptoms but responded to the placebo medication. Subsequently, 42 subjects were given a test meal (identical to the pretest meal). At the onset of symptoms, subjects were randomized to receive activated charcoal or placebo in a blinded fashion. One subject was dropped for not having symptoms after consuming the test meal. Twenty-one subjects received activated charcoal, and 20 subjects received placebo. Every 30 minutes the subject could take an additional dose, up to a maximum of four doses. The subjects rated the degree of overall symptom relief as none, poor, fair, good, or excellent. Riggs reported that 71 percent of the subjects who took activated charcoal rated their relief (of pain and/or cramping and overall symptom relief) "as good to excellent," as compared to only 35 percent who took placebo. Riggs noted, however, that several factors (the time to complete relief, the percentage of subjects with complete relief within 2 hours, and the duration of flatulence) did not demonstrate a statistically significant difference. Riggs stated that these factors did show a "trend" favoring activated charcoal, particularly when only those subjects that had a significant history of symptoms were considered.

The agency concludes that these studies do not provide sufficient evidence to establish that activated charcoal can be generally recognized as safe and effective for use as an OTC antiflatulent or digestive aid. The majority of the studies (Refs. 1 through 5) are not presented in sufficient detail for an indepth agency review. The statistical significance of the findings cannot be verified because of the absence of individual subject data, which have never been provided. Further, the subjects used were inappropriate in most studies. The agency considers it necessary that studies be conducted in a population where all subjects have the condition in question, rather than relying entirely on volunteers in which the condition may or may not occur. Riggs (Ref. 6) was the only investigator that used subjects with a history of meal-induced gastrointestinal discomfort. Although Riggs used the correct type of subjects, the sample size was too small to demonstrate a clinically important difference.

Regarding this sample size, the comment stated that a sample size of 21 subjects in each group provides 90-percent power for detecting a clinically important difference. However, the agency maintains that to obtain a 90-percent power at a 0.05 level (two-sided), the sample size should be approximately 80 subjects per group. If the number were doubled as a precaution, as stated in the protocol, the final sample size would be 160 subjects per group. The study included 21 subjects in the activated charcoal group and 20 subjects in the placebo group.

The study (without invoking considerations of interim analyses and multiple comparisons) was negative for its primary prestated endpoints. While numerically these results are in the right direction, the study was too small to be definitive. Issues such as interim analyses, multiple comparisons, and unspecified subsetting must be considered. With those considerations, the findings in the Riggs study at best might help plan additional studies;

however, they do not change the outcome of this negative trial.

Finally, additional data are needed to establish the dosage range, dosage interval, or dosage duration. In addition, data would be needed to establish whether subsequent dosing is needed because colon gas will eventually dissipate without treatment. Because the submitted data are inadequate to establish the effectiveness of activated charcoal for the relief of symptoms of intestinal distress related to gas, activated charcoal is not a monograph ingredient.

The agency's detailed comments and evaluation of the above data are on file in the Dockets Management Branch (Refs. 7, 8, and 9).

References

(1) Jain, N.K. et al., "Efficacy of Activated Charcoal in Reducing Intestinal Gas: A Double-Blind Clinical Trial," *American Journal of Gastroenterology*, 81:532–535, 1986.

(2) Jain, N.K., V.P. Patel, and C. Pitchumoni, "Activated Charcoal, Simethicone, and Intestinal Gas: A Double-Blind Study," *Annals of Internal Medicine*, 105:61–62, 1986.

(3) Vargo, D., L. Ozick, and M.H. Floch, "The Effect of Activated Charcoal on Breath H_2 Concentration in Subjects With Low and High Baseline H_2 Production," Comment No. CP1, Docket No. 81N–0106, Dockets Management Branch.

(4) Hall, R.G., H. Thompson, and A. Strother, "Effects of Orally Administered Activated Charcoal on Intestinal Gas," *The American College of Gastroenterology*, 75:192–196, 1981.

(5) Potter, T., C. Ellis, and M. Levitt, "Activated Charcoal: In Vivo and In Vitro Studies of Effect on Gas Formation," *Gastroenterology*, 88:620–624, 1985.

(6) Riggs, M.W., "Activated Charcoal Study, Final Report," copy included in Comment No. CP2, Docket No. 81N–0106, Dockets Management Branch.

(7) Letter from W.E. Gilbertson, FDA, to J. Geils, Requa, Inc., Coded LET1, Docket No. 81N–0106, Dockets Management Branch.

(8) Letter from W.E. Gilbertson, FDA, to J. L. Geils, Requa Inc., Coded LET5, Docket No. 81N–0106, Dockets Management Branch.

(9) Letter from W.E. Gilbertson, FDA, to W.R. Weaver, Gulf Bio-Systems, Inc., Coded ANS1, Docket No. 81N–0106, Dockets Management Branch.

2. Two comments stated that activated charcoal could be placed in either the digestive aid monograph or the antiflatulent monograph because the indications for ingredients covered by both monographs are strikingly similar. One of the comments stated that there is very little difference between the indications proposed in the digestive aid tentative final monograph (i.e., "for relief of symptoms of gastrointestinal distress such as * * * fullness, pressure, bloating, or stuffed feeling," (optional: "commonly referred to as gas,") (optional: "pain," and/or "cramping,") "which occur(s) after eating,") (53 FR 2706 at 2713)) and the indications proposed in the amendment to the antiflatulent final monograph (i.e., "alleviates" or "relieves" * * * "bloating," "pressure," "fullness," or "stuffed feeling" "commonly referred to as gas," (53 FR 2716 at 2717)). The comment stated that the only apparent difference is that the digestive aid indication associates the symptoms of gas with the consumption of food, whereas the antiflatulent indication does not. The comment contended that this approach does not make scientific sense because the symptoms of gaseousness are almost always associated with the ingestion of a symptom-provoking meal. The comment argued that consumers will become confused because antiflatulent drug products are able to use the term "antigas" and digestive aid products cannot, even though "antigas" may be the best term to describe the symptomatic relief provided by activated charcoal. The comment requested that FDA allow the term "antigas" as an alternative statement of identity to "digestive aid" because "antigas" is the most accurate and recognizable term describing the symptomatic relief provided by activated charcoal.

The agency has considered activated charcoal in both the antiflatulent and the digestive aid drug products rulemakings. The data submitted to both rulemakings were found to be insufficient to classify activated charcoal as a monograph ingredient for either of these uses. Accordingly, because activated charcoal is not being included in either monograph, the agency does not need to address the statement of identity for this ingredient. Should activated charcoal achieve monograph status in the future, the agency will address its statement of identity at that time.

B. Comments on Testing Digestive Aid Ingredients

3. Two comments stated that FDA should provide clinical protocol design criteria appropriate for OTC digestive aid drug products. The first comment stated that the agency had greatly modified the approach recommended by the Panel for the digestive aid drug category. The comment was concerned that the agency had not published alternative guidelines to clarify how a sponsor should go about investigations to obtain Category I labeling claims.

The second comment stated that if the agency wanted to be helpful in this area it should clearly articulate protocol standards and criteria that can be commented upon, revised if necessary, and then followed. The comment expressed dissatisfaction with certain testing criteria provided at the March 8, 1988, meeting (Ref. 1). The comment felt that the criteria were not applicable to OTC drug products designed to provide symptomatic relief for self-limiting conditions, but rather were applicable to "new drugs" designed to treat serious, chronic, and organic disease. The comment stated that the public and the industry are unaware, as a whole, of what testing criteria are or are not acceptable. The comment argued that if the agency does not know or cannot articulate what label claims it will permit or the protocol criteria it would require to gain Category I status as a digestive aid, it is quite clearly preventing the industry from ever achieving this goal. The comment requested that the agency waive its general policy of not publishing testing guidelines in tentative final monographs and officially state and notify the public, through a written guideline in a revision to the digestive aid tentative final monograph, as to its proposed protocol design criteria to obtain Category I status for OTC digestive aid ingredients.

The Panel provided fairly extensive testing guidelines in its report on OTC digestive aid drug products (47 FR 454 at 485 through 486). The Panel recognized that a generally accepted protocol for the testing of drug products used for the treatment of symptoms of intestinal distress was not available. Further, because of the several categories of drugs marketed for the relief of these symptoms and the different mechanisms of these drugs, the Panel realized that it was unlikely that a single protocol, which would be appropriate for all of these drugs, could be developed. The Panel did not attempt to produce such a protocol. However, the Panel believed that there were important issues that must be considered to ensure proper evaluation of these drugs, and it developed guidelines to aid investigators in designing effectiveness tests. The Panel suggested that deviations from these guidelines be discussed with the appropriate FDA personnel prior to initiation of a study.

The agency did not address testing guidelines in its proposed rule on OTC digestive aid drug products (53 FR 2706 at 2712) and is not providing specific testing guidelines in this document. In revising the OTC drug review

procedures relating to Category III ingredients, published in the Federal Register of September 29, 1981 (46 FR 47730), the agency announced its policy that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. In the same issue of the Federal Register (46 FR 47740), the agency published a policy statement concerning the submission and review of protocols to evaluate an ingredient or condition in the OTC drug review. The agency has stated that it will meet with manufacturers, at their request, to discuss protocols and other testing issues involving conditions that industry is interested in upgrading and to advise industry on the adequacy of proposed testing protocols.

The March 8, 1988, meeting (Ref. 1) referred to by the comment involved a discussion of clinical data submitted to establish the effectiveness of an ingredient for OTC digestive aid or antiflatulent use. The agency's view was that the data were insufficient to justify the dosage range, interval, or duration and the indications requested by the comment. The meeting included a discussion of the patient population to be used in any future studies. The data from the studies and the agency's minutes of this meeting are included as part of the public administrative file for this rulemaking and can be obtained by any interested manufacturer who wishes to ascertain the agency's views. Based on this open public record and the agency's willingness to review testing protocols, the agency sees no need to develop protocol design criteria through notice and comment rulemaking.

Reference

(1) Comment No. MM1, Docket No. 81N–0106, Dockets Management Branch.

C. Comments on Labeling

3. Several comments discussed proposed labeling for OTC digestive aid drug products. Because no active ingredients have been classified as a monograph condition in this final rule for OTC digestive aid drug products, the agency is not addressing the comments' requests at this time. In the future, should a monograph be established for this class of OTC drug products, the agency will consider labeling recommendations, such as those made by the comments, at that time.

II. The Agency's Final Conclusions on OTC Digestive Aid Drug Products

At this time, the agency has determined that no active ingredient has been found to be generally recognized as safe and effective and not misbranded for use as an OTC digestive aid.

In the Federal Register of November 7, 1990 (55 FR 46914), the agency published a final rule establishing that 21 active ingredients for OTC digestive aid use were not generally recognized as safe and effective. That final rule was effective on May 7, 1991, and listed 21 ingredients in § 310.545(a)(8) (currently designated as § 310.545(a)(8)(i)). In the Federal Register of May 10, 1993 (58 FR 27636), the agency published a final rule establishing that 83 additional active ingredients for OTC digestive aid use were not generally recognized as safe and effective. That final rule is effective on November 10, 1993, and lists the 83 ingredients in paragraph (a)(8)(ii). In this final rule, the agency is adding new paragraph (a)(8)(iii) to § 310.545 to include activated charcoal. This final rule expands the list of nonmonograph ingredients and establishes that any OTC digestive aid drug product containing activated charcoal is not generally recognized as safe and effective. Therefore, activated charcoal, when labeled, represented, or promoted for OTC use as a digestive aid, is considered nonmonograph and misbranded under section 502 of the act and is a new drug under section 201(p) of the act, for which an approved application under section 505 of the act and 21 CFR part 314 of the regulations is required for marketing. In appropriate circumstances, a citizen petition to establish a monograph may be submitted under § 10.30 in lieu of an application. In conclusion, any OTC digestive aid drug product containing any of the 105 ingredients listed in § 310.545(a)(8) that is initially introduced or initially delivered for introduction into interstate commerce after the applicable effective date in this paragraph is subject to regulatory action.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (53 FR 2706 at 2713). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC digestive aid drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC digestive aid drug products is not expected to pose such an impact on small businesses. As noted above, two earlier final rules established that a total of 104 active ingredients used in OTC digestive aid drug products were nonmonograph ingredients. This final rule covers one additional ingredient: Activated charcoal. The agency is aware of only a few products that contain this for OTC digestive aid use. Based on the limited number of affected products, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 376); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.545 is amended by adding paragraph (a)(8)(iii); by adding and reserving paragraphs (d)(16) through (d)(20); by adding paragraph (d)(21); and by revising the introductory text of paragraph (d) to read as follows:

§310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(8) * * *

(iii) Charcoal, activated

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(21) of this section.

* * * * *

(21) April 21, 1994, for products subject to paragraph (a)(8)(iii) of this section.

Dated: September 3, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–25841 Filed 10–20–93; 8:45 am]

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federal register

Thursday
October 21, 1993

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 310 and 347

Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 347

[Docket No. 78N–021A]

RIN 0905–AA06

Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph for over-the-counter (OTC) skin protectant drug products and establishing conditions under which OTC astringent drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on OTC astringent drug products that have come to the agency's attention. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: October 21, 1994.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 7, 1982 (47 FR 39412 and 39436), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking for OTC external analgesic drug products and OTC skin protectant drug products. The agency also reopened the administrative records for these rulemakings to allow for consideration of the reports and recommendations on OTC astringent drug products prepared by the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel), which was the advisory review panel responsible for evaluating data on the active ingredients used as astringents. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panel, after deletion of a small amount of trade secret information, were placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

In the **Federal Register** of February 15, 1983 (48 FR 6820), the agency published a notice of proposed rulemaking for OTC skin protectant drug products. The agency issued this notice after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel) and public comments on an advance notice of proposed rulemaking that was based on those recommendations. Interested persons were invited to submit comments by April 18, 1983, new data by February 15, 1984, and comments on the new data by April 16, 1984.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC skin protectant drug products used as astringents was published in the **Federal Register** of April 3, 1989 (54 FR 13490). Interested persons were invited to file by June 2, 1989, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. New data could have been submitted until April 3, 1990, and comments on the new data until June 4, 1990. Interested persons were invited to file comments on the agency's economic impact determination by August 1, 1989.

The agency stated in the proposal that it had determined that the external analgesic and skin protectant uses of OTC astringent drug products are so closely related that it would not serve the public interest to proceed with two separate rulemakings for the same ingredients. Accordingly, the agency proposed to combine the rulemakings for the external analgesic and skin protectant uses of OTC astringent drug products and to place the monograph for these products in the OTC skin protectant monograph. Final agency action occurs with the publication of this final monograph, which is a final rule establishing a monograph for OTC skin protectant drug products used as astringents.

The OTC drug procedural regulations (21 CFR 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA does not use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term "monograph conditions" is used; in place of Categories II or III, the term "nonmonograph conditions" is used.

In the proposed regulation for OTC skin protectant drug products used as astringents (54 FR 13490), the agency advised that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the **Federal Register**. Therefore, on or after October 21, 1994, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an application or abbreviated application (hereinafter called application) approved under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and 21 CFR part 314. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In response to the proposed rule on OTC skin protectant drug products used as astringents, two manufacturers submitted comments. Copies of the comments are on public display in the Dockets Management Branch (address above). Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to

the call-for-data notices published in the Federal Register of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Conclusions on the Comments

A. Comment on Ferric Subsulfate

1. One comment submitted information (Refs. 1 through 32) to support both OTC and professional use of ferric subsulfate solution (Monsel's Solution) as an astringent. The comment suggested consumer use as an astringent/hemostatic agent to arrest bleeding caused by minor surface cuts and grazes; professional use would be to arrest bleeding of superficial skin wounds resulting from minor surgical procedures, such as biopsies and curettage. The comment requested an oral hearing if the agency found the information to be inadequate.

The agency finds the information submitted by the comment insufficient to include ferric subsulfate solution in the final monograph as a topical astringent for either consumer or health professional use.

Most of the references provided refer to the use of ferric subsulfate solution as a hemostatic agent/styptic by medically trained health professionals in a clinical setting after biopsies, minor surgery, and other procedures causing minimal bleeding. None of the data provided suggest that a product containing ferric subsulfate as an astringent/hemostatic agent has ever been used or could be safely used by consumers. Further, the agency is not aware of any other data that show safety or effectiveness for OTC use by consumers. Therefore, the agency has no basis to include ferric subsulfate as an astringent for OTC consumer use in this monograph.

Regarding professional use, the references suggest that there are undesirable side effects and safety risks associated with using ferric subsulfate solution to arrest bleeding due to minor surgical procedures. Several references include reports of ferric subsulfate solution pigmenting the skin. Larson (Ref. 1) states that, although not common, pigmentation of the skin may result from sideroblast deposits or from stimulation of melanocytes. Larson adds that ferric subsulfate has a long-lasting cytotoxic effect that may make subsequent histologic examination of tissue difficult. Olmstead, Lund, and Leonard (Ref. 2) consider ferric subsulfate a histologic nuisance and discourage its use following biopsies of pigmented lesions or tumors that may present diagnostic difficulties. They claim ferric subsulfate promotes artifacts that can be troublesome to the pathologist if rebiopsy of a lesion is necessary, adding that ferric subsulfate may distort or obscure the basic pathologic process. Amazon, Robinson, and Rywlin (Ref. 3) describe the capacity of ferric subsulfate to produce ferrugination of collagen fibers, skeletal muscle, and perichondrium and to produce permanent discoloration of the skin. They state that when there is injury to skeletal muscle and other deep tissues by ferric subsulfate solution, an inflammatory reaction persists at these sites for weeks. They caution that clinicians should be aware that ferric subsulfate solution has demonstrable cytotoxic effects with long-lasting sequelae, and pathologists should be aware of the histopathologic findings that follow application of this solution. Wood and Severin (Ref. 4) suggest that ferric subsulfate may induce granulomas. These granulomas are rarely pigmented and must be differentiated histologically from pigmented neoplasms. Wood and Severin described a case in which a dermal nodule of atypical histiocytes (a macrophage present in connective tissue) developed at the site where ferric subsulfate solution had been applied to a wound 30 days earlier. Duray and Livolsi (Ref. 5) reported that the use of ferric subsulfate solution to achieve hemostasis at a biopsy site can also produce a clinically irregular area of hyperpigmentation accompanied by a pathologic pigmented and cellular dermal reaction. Davis, et al. (Ref. 6) mention the potential effect of ferric subsulfate solution obscuring the basic disease process in the uterine cervix.

Many uses of ferric subsulfate solution were discussed in the references submitted by the comment. However, questions remain concerning which procedures are safe and which are not. Standards for safety of OTC human drugs in § 330.10(a)(4)(i) (21 CFR 330.10(a)(4)(i)) include a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm that may result from abuse under conditions of widespread availability. If ferric subsulfate is cytotoxic as suggested by Larson (Ref. 1), the question of long-term adverse effects for the patient remains unanswered.

The agency finds that permitting the use of ferric subsulfate only in external dermatologic applications would also present difficulties. It is not clear from the references submitted how large a wound may be safely treated with ferric subsulfate solution. Although discoloration of the tissue sometimes results after using the product, there is no indication of the frequency or the severity of this problem. Without such information, the risk to the patient cannot be evaluated.

While ferric subsulfate solution has been in use for over 100 years, its iatrogenic effects (unfavorable response to medical intervention, induced by the intervention itself) have been recognized only recently (Refs. 2, 3, and 4). The agency does not have an adequate safety profile on this ingredient for the various uses suggested by the comment. The safety issues relevant to the product are not adequately addressed by the information provided.

The clinical effectiveness data provided were taken from the medical literature and involved situations where the product was applied by medically trained professionals (Refs. 7 through 32). The references do not provide any clinical information or data on which to base appropriate OTC drug labeling of the product for self-medication. Standards for effectiveness for OTC human drugs in § 330.10(a)(4)(ii) require controlled clinical investigations for proof of effectiveness, and specifically state that isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered. Further, § 330.10(a)(4)(iii) requires the benefit-to-risk ratio of a drug to be considered in determining its safety and effectiveness.

The references include case reports of the uses of ferric subsulfate solution but do not include any controlled clinical studies to show effectiveness. Because other recognized safe astringent products are available for OTC human use and potential risks are associated with the use of ferric subsulfate solution, the benefit-to-risk ratio for ferric subsulfate solution for general consumer use is unfavorable based upon current information. While ferric subsulfate solution may have utility as an astringent/hemostatic when used by health professionals, substantive clinical data are necessary to establish the proper safe and effective conditions for use.

Accordingly, the agency concludes that the data provided are not sufficient to support monograph status for ferric subsulfate solution as an astringent for OTC topical use by consumers or by health professionals. Therefore, ferric subsulfate is not included in this final

monograph. The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Refs. 33 and 34).

Based on the lack of adequate safety and effectiveness data, the agency concludes that an oral hearing before the Commissioner is not warranted.

References

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(5) Duray, P. H., and V. A. Livolsi, "Recurrent Dysplastic Nevus Following Shave Excision," *Journal of Dermatological Surgery and Oncology*, 10:811–815, 1984.

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(9) Ferric Subsulphate Solution, *The National Formulary (IX)*, pp. 214–215, 1950.

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(33) Letter from W. E. Gilbertson, FDA, to D. B. DeVogel, American Dermal Corp., coded LET1, Docket No. 78N–021A, Dockets Management Branch.

(34) Letter from W. E. Gilbertson, FDA, to D. B. DeVogel, American Dermal Corp., coded LET6, Docket No. 78N–021A, Dockets Management Branch.

B. Comments on Hamamelis Water

2. One comment requested that FDA consider the use of specifically denatured alternative preservatives in the manufacture of Hamamelis water. The comment stated that by using its own aromatic and hamamelitannin ingredients as denaturants in the manufacture of Hamamelis water, the preparation would be in compliance with Hamamelis water National Formulary (N.F.) XI. The comment stated that the Bureau of Alcohol, Tobacco, and Firearms (BATF) should give it permission to use those alternative preservatives in the manufacture of Hamamelis water.

OTC drug monographs do not provide special exceptions to methods used to manufacture specific products. At the time that the tentative final monograph was published, Hamamelis water was not included in an official compendium. The agency's reference to "NF XI" in the tentative final monograph (54 FR 13490 at 13493) was intended to provide a standard for the preparation of Hamamelis water. Since that time, the United States Pharmacopeial Convention, Inc. (U.S.P.C.), has initiated development of a current compendial monograph for "Hamamelis water" (Refs. 1 and 2). The agency anticipates that a final monograph will be included in the United States Pharmacopeia (U.S.P.)—N.F. before the effective date of the final monograph for OTC astringent drug products. The proposed new U.S.P.—N.F. monograph is very similar to the former monograph in NF XI and provides a method of preparation. Accordingly, the final monograph for OTC astringent drug products in this document refers to the new U.S.P.—N.F. monograph for Hamamelis water.

The U.S.P.—N.F. provides under "General Notices" (Ref. 3) that a suitable formula of specially denatured alcohol may be substituted for alcohol in the manufacture of pharmacopeial preparations intended for internal or topical use, provided that the denaturant is volatile and does not remain in the finished product. It further states that a finished product that is intended for topical application to the skin may contain specially denatured alcohol, provided that the denaturant is either a normal ingredient or a permissible added substance. Any denatured alcohol used in the preparation of Hamamelis water would need to meet these requirements in order for the product to be marketed OTC in accordance with the final monograph in new part 347.

References

(1) "Pharmacopeial Forum," The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 3855, September through October 1992.

(2) "Pharmacopeial Forum," The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 5266, May through June 1993.

(3) "The United States Pharmacopeia XXII—The National Formulary XVII," The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 3, 1989.

3. One comment requested that the agency reconsider and include in the final monograph several indications for use for Hamamelis water. The comment mentioned that these indications were not included in the agency's notice of proposed rulemaking, but had been recommended by the Miscellaneous External Panel in § 347.52(b)(2) of its advance notice of proposed rulemaking (47 FR 39436 at 39450 and 39451), as follows:

(i) "For use as an astringent for the treatment of bruises, contusions, and sprains."
(ii) "For protecting slight cuts and scrapes."
(iii) "For relieving muscular pains."
(iv) "For treating the pain and swelling of insect bites."
(v) "For use as an astringent for the treatment of skin irritation, sunburn, and external hemorrhoids."

The comment also requested an oral hearing if necessary.

As discussed in the proposed rule for OTC astringent drug products (54 FR 13490 at 13497), the agency is not aware of any data to support the use of Hamamelis water as an astringent for "bruises," "contusions," "sprains," "sunburn," or "relieving muscular pains." The comment did not submit any new data to substantiate any of these claims. Therefore, the agency has no basis for including any of these indications in this final monograph.

Claims for using Hamamelis water for external hemorrhoids are covered in the rulemaking for OTC anorectal drug products. Indications for Hamamelis water products for that use are included in § 346.50(b) of the final monograph for OTC anorectal drug products (21 CFR 346.50(b)). Claims for insect bites, minor cuts, and minor scrapes were proposed in § 347.52(b)(3) of the tentative final monograph (54 FR 13490 at 13497) and appear in new § 347.50(b)(3) of this final monograph. Because the comment did not submit any substantive or new information to support the indications not included in this final monograph, the agency concludes that an oral hearing is not warranted.

II. Summary of Changes From the Proposed Rule

1. In the tentative final monograph the agency proposed to identify Hamamelis water as "NF XI." Now that a new U.S.P. monograph has been established, the agency is identifying Hamamelis water as "U.S.P." (See comment 2.)

2. The definition for an astringent drug product proposed in § 347.3(c) appears in new § 347.3(a) of this final monograph. The active ingredients proposed in § 347.12 appear in new § 347.10 of this final monograph. The labeling of astringent drug products proposed in § 347.52 appears in new § 347.50 of this final monograph.

III. The Agency's Final Conclusions on OTC Astringent Drug Products

Based on available evidence, the agency is issuing a final monograph establishing conditions under which OTC skin protectant drug products used as astringents are generally recognized as safe and effective and not misbranded. Specifically, the agency has determined that the only ingredients that meet monograph conditions are aluminum acetate, aluminum sulfate, and Hamamelis water. All other ingredients considered in this rulemaking have been determined to be nonmonograph. These ingredients include, but are not limited to, acetone, alcohol, alum ammonium, alum potassium, aluminum chlorhydroxy complex (aluminum chloride hexahydrate), aromatics, benzalkonium chloride, benzethonium chloride, benzocaine, benzoic acid, boric acid, calcium acetate, camphor (gum camphor), clove oil (oil of cloves), colloidal oatmeal, cresol, cupric sulfate, eucalyptus oil (oil of eucalyptus), eugenol, ferric subsulfate (Monsel's Solution), honey, isopropyl alcohol, menthol, methyl salicylate (oil of wintergreen), oxyquinoline sulfate, p-t-butyl-m-cresol (para-tertiary-butyl-meta-cresol), peppermint oil (oil of peppermint), phenol (carbolic acid), polyoxyethylene laurate (polyoxyethylene monolaurate), potassium ferrocyanide, sage oil (oil of sage), silver nitrate, sodium borate (borax), sodium diacetate, talc, tannic acid, tannic acid glycerite, thymol, topical starch (starch), zinc chloride, zinc oxide, zinc phenolsulfonate, zinc stearate, zinc sulfate. All of these ingredients except ferric subsulfate (Monsel's Solution) were listed as nonmonograph in § 310.545(a)(18)(ii) (21 CFR 310.545(a)(18)(ii)) in a final rule published in the **Federal Register** of May 10, 1993 (58 FR 27636 at 27642). Ferric subsulfate is being included in that same section in this final rule. Accordingly, any skin protectant drug product labeled, represented, or promoted for use as an OTC astringent that contains any of the ingredients listed in § 310.545(a)(18)(ii) or that is not in conformance with this final monograph (new part 347) is considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)) and misbranded under section 502 of the act (21 U.S.C. 352) and may not be marketed for this use unless it is the subject of an approved application under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314. An appropriate citizen petition to amend the monograph may also be submitted under 21 CFR 10.30 in lieu of an application. Any OTC skin protectant drug product for use as an astringent that is initially introduced or initially delivered for introduction into interstate commerce after the effective dates of § 310.545(a)(18)(ii) or this final rule that is not in compliance with the regulations is subject to regulatory action. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (51 FR 27346 at 27362, July 30, 1986). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC skin protectant drug products used as astringents, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC skin protectant drug products used as astringents is not expected to pose such an impact on small businesses. This final rule will require some relabeling of products containing monograph ingredients. Manufacturers will have 1 year to implement this new labeling. Nonmonograph ingredients except ferric subsulfate (Monsel's Solution) were addressed previously when § 310.545(a)(18)(ii) was published.

Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 347

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 is revised to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

2. Section 310.545 is amended in paragraph (a)(18)(ii) by alphabetically adding the entry "Ferric subsulfate (Monsel's Solution)," by revising paragraph (d)(11), and by adding new paragraph (d)(22) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(18) * * *

(ii) * * *

* * * * *

Ferric subsulfate (Monsel's Solution)

* * * * *

(d) * * *

(11) November 10, 1993, for products subject to paragraph (a)(18)(ii) of this section, except products that contain ferric subsulfate.

* * * * *

(22) April 21, 1993, for products subject to paragraph (a)(18)(ii) of this section that contain ferric subsulfate.

3. Part 347 is added as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—Astringent Drug Products

Sec.

347.1 Scope.
347.3 Definitions.
347.10 Astringent active ingredients.
347.50 Labeling of astringent drug products.

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

Subpart A—Astringent Drug Products

§ 347.1 Scope.

(a) An over-the-counter skin protectant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 347.3 Definitions.

As used in this part:

(a) *Astringent drug product* means a drug product that is applied to the skin or mucous membranes for a local and limited protein coagulant effect.

(b) [Reserved]

§ 347.10 Astringent active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

(a) Aluminum acetate, 0.13 to 0.5 percent (depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 0.13 to 0.5 percent aluminum acetate).

(b) Aluminum sulfate, 46 to 63 percent (the concentration is based on the anhydrous equivalent).

(c) Hamamelis water, U.S.P.

§ 347.50 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "astringent."

(b) *Indications.* The labeling of the product states, under the heading "Indications" any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b) may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing aluminum acetate identified in § 347.10(a).* "For temporary relief of minor skin irritations due to" (select one or more of the following: "poison ivy," "poison oak," "poison sumac," "insect bites," "athlete's foot," or "rashes caused by soaps, detergents, cosmetics, or jewelry").

(2) *For products containing aluminum sulfate identified in § 347.10(b) for use as a styptic pencil.* "Stops bleeding caused by minor surface cuts and abrasions as may occur during shaving."

(3) *For products containing Hamamelis water identified in § 347.10(c).* (i) "For relief of minor skin irritations due to" (select one or more of the following: "insect bites," "minor cuts," or "minor scrapes").

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only. Avoid contact with the eyes."

(2) *For products containing aluminum acetate identified in § 347.10(a) or hamamelis water identified in § 347.10(c).* "If condition worsens or symptoms persist for more than 7 days, discontinue use of the product and consult a" (select one of the following: "physician" or "doctor").

(3) *For products containing aluminum acetate identified in § 347.10(a) used as a compress or wet dressing.* "Do not cover compress or wet dressing with plastic to prevent evaporation."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing aluminum acetate identified in § 347.10(a)*—(i) *For products used as a soak.* "For use as a soak: Soak affected area in the solution for 15 to 30 minutes. Discard solution after each use. Repeat 3 times a day."

(ii) *For products used as a compress or wet dressing.* "For use as a compress or wet dressing: saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Discard solution after each use. Repeat as often as necessary."

(2) *For products containing aluminum sulfate identified in § 347.10(b) for use as a styptic pencil.* "Moisten tip of pencil with water and apply to the affected area. Dry pencil after use."

(3) *For products containing hamamelis water identified in § 347.10(c).* "Apply to the affected area as often as necessary."

Dated: August 26, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–25739 Filed 10–20–93; 8:45 am]

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Thursday
October 21, 1993

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 328

Drug Products Intended for Oral Ingestion That Contain Alcohol; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 328

[Docket No. 93N–0107]

Over-the-Counter Drug Products Intended for Oral Ingestion That Contain Alcohol

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would establish a maximum concentration limit for alcohol (ethyl alcohol) as an inactive ingredient in over-the-counter (OTC) drug products intended for oral ingestion (0.5 percent alcohol for children under 6 years of age, 5 percent alcohol for children 6 to under 12 years of age, and 10 percent alcohol for anyone 12 years of age and over). In addition, the proposal requires that the alcohol content be stated conspicuously or prominently on the principal display panel (front) of product labeling. FDA is issuing this notice of proposed rulemaking after considering recommendations from its OTC Drugs Advisory Committee (the Committee).

DATES: Written comments by January 19, 1994. Written comments on the agency's economic impact determination by January 19, 1994. The agency is proposing that any final rule that may issue based on this proposal become effective 12 months after the date of publication in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855, 301–594–5000.

SUPPLEMENTARY INFORMATION: Alcohol is present as an inactive ingredient (e.g., solvent, preservative) in many different types of OTC drug products that are orally ingested: Analgesic, cough-cold, laxative, menstrual, and other drug products. The use of alcohol in those products has been discussed in several rulemakings for OTC drug products, with the majority of the discussion in the rulemaking for OTC cough-cold drug products.

I. Rulemaking for OTC Cough-Cold Drug Products

The Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) took the position that medications administered to children should contain either a minimum amount of alcohol or none at all. (See the **Federal Register** of September 9, 1976, 41 FR 38312 at 38333.) The Panel concluded that alcohol in pediatric formulations should be maintained at the lowest possible concentration, that products should be formulated without alcohol if pharmaceutically possible, and that cough-cold drug products containing alcohol greater than 10 percent weight-to-weight should not be given to children under 6 years of age except under the advice and supervision of a physician.

Subsequently, FDA asked the American Academy of Pediatrics Committee on Drugs (AAP/CD) to evaluate the use of alcohol in OTC drug products for children. The AAP/CD stated that ideally medicinal products intended for use in children should contain no alcohol. However, if alcohol is required to solubilize the active ingredients in a product intended for use in children, the AAP/CD made the following recommendations to FDA: (1) OTC liquid preparations should be limited to a maximum of 5 percent volume-to-volume alcohol, (2) physician supervision is suggested for children less than 6 years of age who use OTC preparations containing alcohol, (3) the amount of alcohol contained in any medicinal preparation should not be capable of producing a blood alcohol concentration greater than 25 milligrams (mg) per 100 milliliters (mL) after a single recommended dose, (4) appropriate intervals between doses should be prescribed to prevent the accumulation of blood alcohol, (5) the packaged volume of alcohol-containing products should be kept to a reasonable minimum to prevent potential lethal ingestions, and (6) safety closures should be used for medications with greater than a 5-percent alcohol content (Ref. 1). The AAP/CD concluded that pediatricians and other health care providers should be aware of the widespread presence of alcohol in liquid medications and its potential toxicity. The AAP/CD recommended that continued efforts be made to remove alcohol from liquid preparations intended for children.

In the tentative final monograph for OTC cough-cold combination drug products, the agency stated that it was considering adopting the AAP/CD recommendations and invited public comment. (See the **Federal Register** of August 12, 1988, 53 FR 30522 at 30528 and 30529.) The agency cited data in support of the proposition that alcohol depresses the central nervous system over a wide range of doses, that threshold effects are observed at blood levels of 20 to 50 mg per 100 mL, and that a detectable impairment of vision occurs at a blood level of about 15 mg per 100 mL (Ref. 2).

In response, the Nonprescription Drug Manufacturers Association (NDMA) objected to many of the AAP/CD recommendations. NDMA contended that alcohol has a number of legitimate uses in formulating OTC drug products, that it: (1) Enhances flavor, (2) provides palatability to distasteful ingredients, especially those extracted from natural sources, (3) acts as an effective preservative against microbial growth and chemical change, (4) enhances the antimicrobial potency of other preservatives that may be needed in a product, (5) maintains stability more effectively with less added volume than water-miscible alternatives, and (6) is less toxic than most alternative solvents. NDMA contended that AAP/CD's recommendation of a 5-percent alcohol limit is unduly restrictive in relation to the dose and package volumes of current OTC drug products. NDMA concluded that the alcohol limit proposed by AAP/CD would not appear to offer greater safety to children when OTC drug products are taken at recommended doses or accidentally ingested.

The agency subsequently received letters from groups concerned about the presence of alcohol in OTC drug products (Refs. 3, 4, and 5). The American Psychiatric Association (Ref. 3) suggested that the agency minimize the alcohol content in medicines. The National Council on Alcoholism and Drug Dependence, Inc. (Ref. 4) stated that drug products should contain only the amount of alcohol that is minimally necessary, as determined solely by the physical and chemical characteristics of the medication. The Consumer Protection Board of the State of New York (Ref. 5) urged the agency to determine whether manufacturers of alcohol-containing OTC drug products could obtain the same results without the use of alcohol.

The subject of alcohol in OTC drug products was also discussed in the final monograph for OTC antihistamine drug products (57 FR 58356, December 9, 1992). This monograph includes warnings in § 341.72(c)(3) (21 CFR 341.72(c)(3)) that advise consumers to avoid alcoholic beverages while taking

products containing any of the following antihistamines: Brompheniramine maleate, chlorcyclizine hydrochloride, chlorpheniramine maleate, dexbrompheniramine maleate, dexchlorpheniramine maleate, diphenhydramine citrate, diphenhydramine hydrochloride, phenindamine tartrate, pheniramine maleate, pyrilamine maleate, thonzylamine hydrochloride, or triprolidine hydrochloride. Those warnings advise that the product may cause drowsiness and that alcohol may increase the drowsiness effect.

II. The OTC Drugs Advisory Committee Meeting

Because of the concerns discussed above, the agency asked its OTC Drugs Advisory Committee to advise the agency on the appropriate alcohol content of OTC drug products. On December 17, 1992 (Ref. 6), the Committee was presented information on the following topics: Types of OTC drug products that contain alcohol, the pharmaceutical role of alcohol, the pharmacokinetics and pharmacodynamics of alcohol, numerous safety issues concerning alcohol and its use in OTC drug products, possible alcohol content limitations, and nonalcohol formulation alternatives. The Committee considered the benefits and risks of alcohol in OTC drug products and whether limits should be placed on the alcohol concentration in these products. The Committee discussed the bases for alcohol content limitations and sought to determine whether there should be differences in requirements for products intended to be used by consumers of different ages: (1) Under the age of 6 years, (2) age 6 to under 12 years, (3) for adult use (over 12), and (4) for use by the elderly. The Committee considered whether alcohol in OTC drug products contributes significantly to alcohol abuse, what effect it has on alcoholics and children of alcoholics, and what specific actions could be recommended to reduce any risks. The Committee also addressed the pharmaceutical uses of alcohol in OTC drug products and possible alternative solvents or vehicles.

A transcript (Ref. 6) containing the various presentations and the Committee's discussion is on public display in the Dockets Management Branch (address above). A summary of the presentations and discussion follows.

Alcohol has been well recognized as a pharmaceutical excipient and is most commonly used as a solvent in the formulation of oral drug products. Certain drugs are insoluble in water and must be delivered in an alternate vehicle. Alcohol is the preferred solvent because of its high relative ability to dissolve many water-insoluble ingredients, including flavors used in OTC drug products. Alcohol is also used with other solvents, such as glycols and glycerin, to reduce the amount of solvent needed in a product. Alcohol increases the antimicrobial activity of glycol solvents. Alcohol is also used as a preservative to ensure stability, and as a copreservative in conjunction with parabens, benzoates, sorbates, or ethylenediaminetetraacetic acid to broaden and enhance the antimicrobial activity of the preservative system. For example, alcohol shows less pH dependency than the benzoates and parabens and, as a copreservative, makes antimicrobial activities of parabens and benzoates less dependent on the product's pH. Thus, the alcohol-benzoate or alcohol-paraben preservative system can be used in a broader range of products than benzoate or paraben preservatives alone. At a 10-percent concentration, alcohol prevents inactivation of parabens by nonionic surfactants.

Although alcohol offers certain advantages in formulation, as discussed above, one Committee member noted that it is not an absolute pharmaceutical necessity. Glycerin, polyethylene glycol, and propylene glycol can be used as substitutes. However, these other ingredients lack the solvent power of alcohol. Polyethylene glycol and propylene glycol are on FDA's Generally Recognized As Safe (GRAS) list of food additive ingredients. However, ingestion of large amounts of propylene glycol has resulted in lactic acidosis (increased blood lactic acid concentrations). Also, when propylene glycol is eliminated from the body, isopropyl alcohol is a metabolic byproduct. When excess amounts of glycerin are ingested, hyperosmolar nonketotic coma, diabetic acidosis, pulmonary edema, and minor symptoms of headache, nausea, vomiting, and dizziness can occur.

The pharmacokinetics and pharmacodynamic effects of alcohol were discussed by the Committee. Alcohol at significant blood concentration levels exhibits zero order (or saturable) pharmacokinetics, i.e., the quantity of alcohol elimination per unit of time is constant and is not proportional to the concentration of alcohol in the body. Alcohol does not have a defined half-life because the half-life changes according to the quantity of alcohol remaining in the body. The amount of alcohol does not decrease by a constant fraction per unit time, but decreases by a constant amount per unit time. Zero order pharmacokinetics can create a blood alcohol concentration that is no longer proportional to the dose, i.e., a small increase in dose may have a large increase in the blood alcohol concentration. One Committee member stated that several studies have shown that there is little difference in alcohol pharmacokinetics for the geriatric population. Also, there is insufficient scientific data in the literature to demonstrate the pharmacokinetics of alcohol in the pediatric population.

In acute alcohol intoxication, lactic acidosis develops, with hypoglycemia occurring in some people. These effects pose a serious toxicologic problem, especially in children who consume alcohol-containing products. The principal action of alcohol is central nervous system depression. As increasing levels of depression occur, changes in perception and motor incoordination occur and, finally, coma and loss of dependent reflexes can occur. Different effects occur as the blood alcohol concentration increases: At 50 mg per deciliter (dL), some motor function impairment occurs; at about 80 mg per dL, the motor impairment becomes very evident; at about 200 mg per dL, significant central nervous system depression occurs; at 400 mg per dL, respiratory failure can occur. Death can occur due to respiratory failure or as a result of pulmonary aspiration of gastric contents.

Individuals can vary greatly in their sensitivity to alcohol, i.e., in the concentration that produces a particular intensity of effect. Individuals who have developed a tolerance to alcohol will experience a less intense effect at a particular concentration than normal, nontolerant individuals.

Other effects of alcohol are cutaneous vasodilation (a relatively small effect on the cardiovascular system), withdrawal syndrome, stimulation of gastric acid secretion, and stomach irritation. Alcohol is a teratogen. Fetal alcohol syndrome has been well described in babies of women who consume large amounts of alcohol during certain stages of pregnancy.

A number of studies have correlated alcoholism with age, sex, race, drinking pattern, socioeconomic status, family history, genetic factors, environmental factors, consumption, and cirrhosis mortality and morbidity. A large number of case reports on hepatic and renal injury have involved simultaneous use of alcohol and OTC drugs, particularly acetaminophen. Large doses of acetaminophen (greater than recommended in labeling) taken with

alcohol can produce potentially fatal hepatic and renal necrosis. Data from studies in monkeys suggest that alcohol increases the reinforcing effects of other drugs in terms of implications for human behavior and increased liability for abuse. Alcoholics are known to drink mouthwashes that contain alcohol, and it is not unusual for individuals in addiction treatment programs to use OTC medications that are formulated with alcohol as a source of alcohol.

Children's exposure to medicines having a high alcohol content raises special concerns. However, one Committee member noted that there are little data on the use of alcohol in children, probably because alcohol intake is not legal in children or in young adults under 18 to 21 years of age. In March 1984, the AAP/CD (Ref. 1) established that a child's blood alcohol concentration should not exceed 25 mg per dL following a single dose of alcohol-containing medication. The AAP/CD estimated the volumes (mL) of alcohol preparations predicted to produce a blood alcohol concentration of 25 mg/dL in different aged children, as stated in the following chart:

ESTIMATED VOLUMES (ML) OF ALCOHOL PREPARATION REQUIRED TO PRODUCE A BLOOD ALCOHOL CONCENTRATION OF 25 MG PER DL

Percent absolute ethanol (v/v) in product	Age (weight)					
	2 yr (12 kg)	4 yr (16 kg)	6 yr (21 kg)	8 yr (27 kg)	10 yr (32 kg)	12 yr (38 kg)
2.5	91	122	160	205	243	289
5.0	46	61	80	103	122	144
7.5	30	41	53	68	81	96
10.0	23	30	40	51	61	72
12.5	18	24	32	41	49	58
20.0	11	15	20	26	30	36
25.0	9	12	16	21	24	29

These figures are based on data taken from adults and, therefore, are strictly hypothetical with respect to children. Nonetheless, after this paper was published, many manufacturers voluntarily reduced the amount of alcohol in their products. The AAP/CD report did not endorse the use of alcohol in orally ingested OTC drug products intended for use in children. The report stated that it was desirable to have no alcohol in medicinal products intended for use in children and recommended that a continued effort be made to remove alcohol from these products.

It was noted by one Committee member that the concentration of alcohol in OTC drug products was not as much a concern as the palatability of the product and the willingness of a child to take the product. Once ingested, alcohol's effects are the same regardless of the source or vehicle. Between 1987 and 1991, 17,000 cases of ingestion of alcohol-containing mouthwashes were reported to poison control centers, with 39 cases experiencing major (life-threatening) effects. Several of these cases involved children, and there were four deaths, including one child. Out of 145,000 reported incidents involving alcohol in perfume, cologne, and aftershave, only 14 cases were classified as major, with no deaths reported.

According to NDMA, reports from the American Association of Poison Control Centers National Data Collection System showed no deaths in children less than 6 years of age due to accidental ingestion of alcohol-containing OTC drug products intended for oral ingestion. Data from poison control centers do not indicate a widespread acute intoxication problem from the accidental ingestion of alcohol in OTC drug products. For example, in a study monitored by the Maryland Poison Control Center, covering the period from June 1989 to June 1992, there was no major difference in adverse effects between products containing alcohol (10 to 25 percent) and alcohol-free products. No deaths, major effects, or moderate effects were reported. Most ingestions involving products containing alcohol were in the 2 ounce (oz) range, with the maximum ingestion reported being 4 oz in a slightly older child.

A representative from Canada stated that manufacturers of pediatric medications marketed in Canada are encouraged to use other suitable solvents, and they are required to justify the use of alcohol. When use can be justified, the concentration of alcohol should not exceed 5 percent volume-to-volume, with the amount of alcohol contained in the product not capable of producing a blood concentration greater than 25 mg per dL per dose, when taken as directed.

NDMA proposed to the Committee the following alcohol concentration limits for OTC monographed drug products intended for oral ingestion: 10 percent alcohol volume-to-volume for adults and children ages 12 and over, except in cases where higher concentrations of alcohol must be used (e.g., plant extracts); up to 5 percent volume-to-volume for children 6 to under 12 years of age, and alcohol-free products (defined as less than 0.5 percent alcohol) for children under 6 years of age (Ref. 7). These limits would be implemented by the OTC drug industry on a voluntary basis. The NDMA program also includes current agency required warnings (such as for antihistamines, as discussed above) and additional direction statements for OTC alcohol-containing drug products. According to NDMA, directions for use of products containing between 5 and 10 percent alcohol should convey that physician supervision is recommended for children under 12 years of age. For pediatric products with an alcohol concentration above 0.5 percent, directions for use should state that supervision of a physician is recommended for children under 6 years of age. NDMA member companies with affected OTC drug products intend to make these changes "as soon as practicable," with the goal of voluntary compliance for reformulating and labeling to the new 5- and 10-percent alcohol limitations targeted for November 1993. The goal for the reformulation and labeling of alcohol-free OTC drug products is December 1994.

Reference was made to the Cough-Cold Panel's recommendation that products containing alcohol 10 percent weight-to-weight, equivalent to about 12 to 13 percent volume-to-volume, not be given to children under 6 years of age, except under the advice and supervision of a physician. NDMA concluded that its proposed maximum alcohol concentration of 10 percent volume-to-volume is more conservative than that recommended by the Cough-Cold Panel.

The Committee members concluded that OTC drug products for oral ingestion should not contain more than the minimum amount of alcohol needed as a solvent for the active ingredient, for preservative purposes, or for taste enhancement.

The Committee agreed with NDMA's recommendations as follows:

1. For persons 12 years of age and above, a maximum alcohol concentration up to and including 10 percent volume-to-volume. (While the Committee members could not identify any specific data that showed a difference in safety between 5 and 10 percent concentrations of alcohol in products, they generally preferred that a lower concentration, closer to 5 percent, be used whenever possible.)

2. For children age 6 to under 12, a maximum alcohol concentration up to and including 5 percent volume-to-volume. (However, the Committee stated that a lower concentration, closer to 0.5 percent, should be used whenever possible.)

3. For children under 6 years of age, a maximum alcohol concentration up to and including 0.5 percent volume-to-volume.

The Committee recognized that metabolism and toxicity data in children under 12 years of age were lacking, but decided that these recommendations were reasonable and the best guidelines to follow at this time. For products intended for use in children under 6 years of age, the Committee recommended that only products containing no alcohol be labeled "alcohol free." Some Committee members felt that all products for use in children under 12 years of age should be alcohol free because a number of these products have been reformulated to remove the alcohol, which suggests that no alcohol is needed for the formulation of these products.

The Committee concluded that the only exception to the 10 percent maximum alcohol concentration should be those products that cannot be formulated with a 10 percent or lower alcohol concentration (e.g., plant extracts). The Committee recommended that such products obtain a special exemption from FDA based upon suitable justification.

The Committee also discussed where the alcohol content should be disclosed in the product's labeling, e.g., the principal display panel (front) or the product information panel (not usually the front). Several Committee members, who felt that the information should be conspicuous, favored placement of this information on the principal display panel. However, no formal vote was taken on this issue.

III. The Agency's Tentative Conclusions on the Committee's Recommendations

The agency agrees with the Committee's recommendations to limit the use of alcohol in OTC drug products. The agency has considered whether such limits should be voluntary, as suggested by NDMA. The agency is aware that a voluntary program may not involve all OTC drug manufacturers and their products. Further, a voluntary program would not be enforceable by the agency. Therefore, the agency is proposing that alcohol limitations and related labeling requirements for all OTC drug products intended for oral ingestion be implemented by regulation. These regulations would apply to OTC drug products regulated under the monograph system (21 CFR parts 330 to 358), and those approved under new drug applications.

The agency concurs with the Committee that OTC drug products for oral ingestion should not contain more than the minimum amount of alcohol needed as a solvent for the active ingredient, for preservative purposes, or for taste enhancement. In keeping with public health goals, the agency strongly encourages the lowest amount of alcohol necessary for pharmaceutical purposes to be used. Lower concentrations would help limit potential misuse of products for their alcohol content and reduce undesirable alcohol ingestions by adolescents. Therefore, a 5-percent alcohol concentration limit is preferred, even though no specific data have been presented to demonstrate a difference in safety between 5 and 10 percent alcohol in OTC drug products intended for oral ingestion.

However, in this document, based on the Committee's concurrence with NDMA's proposal for OTC drug products intended for oral ingestion that contain alcohol, the agency is proposing: (1) A 10-percent alcohol limit for OTC drug products intended for adults and children 12 years of age and over, (2) a 5-percent alcohol limit for OTC drug products intended for children 6 to under 12 years of age, and (3) a 0.5-percent alcohol limit for OTC drug products intended for children under 6 years of age. The agency invites specific comment on the proposed 10-percent maximum alcohol concentration, including specific data and reasons that might support lowering this concentration to a 5-percent limit.

The agency notes that NDMA suggested that products containing up to 0.5 percent alcohol be called "alcohol free." However, this designation would be misleading because it infers that the product contains no alcohol whatsoever. Individuals taking an alcohol-deterrent medication, such as disulfiram, could suffer untoward reactions by ingesting an alcohol-containing drug product labeled as "alcohol free" that actually contained a small amount of alcohol. Therefore, the agency is proposing that the term "alcohol free" mean that the product contains no alcohol at all. The agency also invites specific comment on this labeling term.

The agency agrees with the NDMA suggestion (see Section II of this document) that products containing alcohol include additional directions regarding supervised use by a physician when the product is used in children below a certain age. However, it is possible that these age limitations based on alcohol content may differ from age limitations based on other ingredients contained in the product that are included in an OTC drug monograph. Therefore, the agency is including a provision in the proposed regulation that if age limitation statements differ, the direction referring to the higher age limitation should be used. For example, for an OTC drug product containing the antihistamine ingredient diphenhydramine hydrochloride and 10 percent alcohol, the antihistamine monograph requires labeling for diphenhydramine products to advise users to consult a physician for use in children under 6 years of age. The proposed alcohol regulation would require the labeling direction to consult a physician for use in children under 12 years of age for products containing between 5 and 10 percent alcohol. In this case, the direction for the higher age limitation (i.e., to consult a physician for use in children under 12 years of age) would be required in the product's labeling, and the labeling could not include directions for children age 6 to under 12. A provision to use this higher age-limitation labeling is being included in the proposed regulation.

The agency has considered where the alcohol content of a product should be stated in labeling. The agency believes that consumers need to know this information when they purchase the product. The agency is concerned that consumers do not necessarily read all of a product's labeling at the time of purchase. The agency believes that the product's alcohol content should be prominently and conspicuously displayed in the product's labeling, and that this information should be readily available and visible to consumers at the time of purchase. Therefore, the agency

is proposing that this information appear on the front (principal) display panel of the product's labeling and that the information be in a size reasonably related to the most prominent printed matter on that panel. In addition, some manufacturers are presently placing the term "alcohol free" on their products' principal display panel and will likely do so for new or revised products containing no alcohol. Therefore, to facilitate comparison, the agency believes that the alcohol content of products containing alcohol should also appear on the principal display panel. Further, because section 502(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)) requires that the quantity, kind, and proportion of alcohol be stated on a drug product's label, the alcohol content will also need to appear on the immediate container label when the immediate container (e.g., a glass bottle) is marketed in another retail package, e.g., an outer box. This dual labeling of alcohol content will be beneficial should a consumer discard the outer package. The agency invites specific comment on the location of this information in OTC drug product labeling, particularly from consumers who have an interest in this type of information.

The agency is proposing that any final rule that may issue based on this proposal become effective 12 months after the date of publication in the **Federal Register**. Based on the time that this is likely to occur, the effective date would be consistent with NDMA's goals for its voluntary program, which are November 1993 for the reformulation and labeling of affected OTC drug products to the new 5- and 10-percent alcohol limitations, and December 1994 for the reformulation and labeling of alcohol-free OTC drug products.

If the agency determines that any condition included in the final regulation should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular condition not in conformance with the final regulation, a shorter deadline may be set for removal of that condition from OTC drug products. The agency encourages manufacturers to implement voluntarily the provisions of this proposed rule at their earliest convenience.

Within the OTC drug product marketplace, the agency is not aware of a significant number of products that would be affected due to their alcohol content as an inactive ingredient. Products that would be affected consist of a limited number of OTC liquid cough-cold, internal analgesic, and laxative drug products. Therefore, the agency concludes that the economic impact of this proposed rule, if implemented, would be minimal and that the proposed rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC drug products intended for oral ingestion that contain alcohol as an inactive ingredient. Types of impact may include, but are not limited to, costs associated with reformulating, product (stability) testing, repackaging, and relabeling. Comments regarding the impact of this rulemaking on OTC drug products intended for oral ingestion that contain alcohol as an inactive ingredient should be accompanied by appropriate documentation. A period of 90 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before January 19, 1994, submit to the Dockets Management Branch (address above) written comments on the proposed amendment and on the agency's economic impact determination. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) American Academy of Pediatrics, Committee on Drugs, "Ethanol in Liquid Preparations Intended for Children," Pediatrics, 73:405–407, 1984.

(2) Maling, H.M., "Toxicology of Single Doses of Ethyl Alcohol," in International Encyclopedia of Pharmacology and Therapeutics, Pergamom Press, Elmsford, NY, 2:227–299, 1970.

(3) Letter from M. Sabshin, Medical Director, American Psychiatric Association to FDA, July 28, 1992.

(4) Letter from P. Wood, National Council on Alcoholism and Drug Independence, Inc., to FDA, July 30, 1992.

(5) Letter from R.M. Kessel, State of New York Consumer Protection Board to FDA, July 12, 1991.

(6) Transcript of Open Proceedings of OTC Drugs Advisory Committee, December 17, 1992.

(7) Alcohol Content Limitation for Monograph'd OTC's Intended for Oral Ingestion, Nonprescription Drug Manufacturers Association, presented at OTC Drugs Advisory Committee meeting, December 17, 1992.

List of Subjects in 21 CFR Part 328

Alcohol, Drugs, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended to add part 328 as follows:

PART 328—OVER-THE-COUNTER DRUG PRODUCTS INTENDED FOR ORAL INGESTION THAT CONTAIN ALCOHOL

Subpart A—General Provisions

Sec.
328.1 Scope.
328.3 Definitions.

Subpart B—Ingredients

328.10 Alcohol.

Subpart C—Labeling

328.50 Principal display panel of all OTC drug products intended for oral ingestion that contain alcohol.

Authority: Secs. 201, 301, 501, 502, 503, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 371).

Subpart A—General Provisions

§ 328.1 Scope.

Reference in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 328.3 Definitions.

As used in this part:

(a) *Alcohol* means the substance known as ethanol, ethyl alcohol, or Alcohol USP.

(b) *Inactive ingredient* means any component of a product other than an active ingredient as defined in § 210.3(b)(7) of this chapter.

Subpart B—Ingredients

§ 328.10 Alcohol.

(a) Any over-the-counter (OTC) drug product intended for oral ingestion shall not contain alcohol as an inactive ingredient in concentrations that exceed those established in this part, unless a specific exemption, as provided in paragraph (e) of this section, has been approved.

(b) For any OTC drug products intended for oral ingestion and labeled for use by adults and children 12 years of age and over, the amount of alcohol in the product shall not exceed 10 percent.

(c) For any OTC drug product intended for oral ingestion and labeled for use by children 6 to under 12 years of age, the amount of alcohol in the product shall not exceed 5 percent.

(d) For any OTC drug product intended for oral ingestion and labeled for use by children under 6 years of age, the amount of alcohol in the product shall not exceed 0.5 percent.

(e) The Food and Drug Administration will grant an exemption from paragraphs (b), (c), and (d) of this section where appropriate, upon petition under the provisions of § 10.30 of this chapter. Appropriate cause, such as a specific solubility or manufacturing problem, must be adequately documented in the petition. Decisions with respect to requests for exemption shall be maintained in a permanent file for public review by the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

Subpart C—Labeling

§ 328.50 Principal display panel of all OTC drug products intended for oral ingestion that contain alcohol.

(a) The amount (percentage) of alcohol present in a product shall be stated in terms of percent volume of absolute alcohol at 60 °F (15.56 °C) in accordance with § 201.10(d)(2) of this chapter.

(b) A statement expressing the amount (percentage) of alcohol present in a product shall appear prominently or conspicuously on the "principal display panel," as defined in § 201.60 of this chapter. For products whose principal display panel is on the immediate container label and that are not marketed in another retail package (e.g., an outer box), the statement of the percentage of alcohol present in the product shall appear prominently or conspicuously on the "principal display panel" of the immediate container label.

(c) For products whose principal display panel is on the retail package and the retail package is not the immediate container, the statement of the percentage of alcohol present in the product shall also appear on the immediate container label; it may appear anywhere on that label in accord with section 502(e) of the Federal Food, Drug, and Cosmetic Act.

(d) The statement expressing the amount (percentage) of alcohol present in the product shall be in a size reasonably related to the most prominent printed matter on the panel or label on which it appears, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) For a product to state in its labeling that it is "alcohol free," it must contain no alcohol (0 percent).

(f) For any OTC drug product intended for oral ingestion containing over 5 percent alcohol and labeled for use by adults and children 12 years of age and over, the labeling shall contain the following statement in the directions section: "Consult a physician for use in children under 12 years of age."

(g) For any OTC drug products intended for oral ingestion containing over 0.5 percent alcohol and labeled for use by children ages 6 to under 12 years of age, the labeling shall contain the following statement in the directions section: "Consult a physician for use in children under 6 years of age."

(h) When the direction regarding age in paragraph (f) or (g) of this section differs from an age-limiting direction contained in any OTC drug monograph in this chapter, the direction containing the higher age limitation shall be used.

Dated: July 30, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

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