Sunshine Act Meetings

Federal Register
Vol. 55, No. 92
Friday, May 11, 1990

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).

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: Monday, May 7, 1990, 11:00 a.m.

LOCATION: Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, Maryland.

STATUS: Closed to the Public.

MATTERS TO BE CONSIDERED:
Enforcement Matter OS# 5454

The staff and the Commission will discuss issues related to enforcement matter OS# 5454.

The Commission decided by unanimous vote that agency business required scheduling this meeting without the normal seven days notice.

For a Recorded Message Containing the Latest Agenda Information, call: 301–492–5709

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207; 301–492–6800.

Dated: May 7, 1990.

Sheldon D. Butts,

Deputy Secretary.

[FR Doc. 90–11184 Filed 5–9–90; 2:19 pm]

BILLING CODE 6355–01–M

LEGAL SERVICES CORPORATION

Presidential Search Committee

Notice

TIME AND DATE: A meeting of the Presidential Search Committee will be held on May 20, 1990. The meeting will commence at 1:00 p.m.

PLACE: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Potomac I & II, Arlington, VA 22202, (703) 418–1234.

STATUS OF MEETING: Open [A portion of the meeting may be closed subject to the recorded vote of a majority of the Board of Directors to discuss matters related to Presidential Search as authorized under the Government in the Sunshine Act [5 U.S.C. 552b (c) (2), (6), and (9)(B) and 45 CFR 1622.5 (a), (e), and (g)]].

MATTERS TO BE CONSIDERED: A portion of the meeting may be closed for the reasons cited above, subject to an advance recorded vote of a majority of the Board of Directors.

1. Matters Related to Presidential Search.

(a) Review of Resumes.
(b) Review of Procedures.
(c) Review of Standards/Qualifications.

CONTACT PERSON FOR MORE INFORMATION: Maureen R. Bozell, Executive Office, (202) 863–1839.

Date Issued: May 9, 1990.

Maureen R. Bozell,

Corporation Secretary.

[FR Doc. 90–11207 Filed 5–9–90; 3:44 pm]

BILLING CODE 7050–01–M

RESOLUTION TRUST 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 on Tuesday, May 8, 1990, at 2:22 p.m., the Board of Directors of the Resolution Trust Corporation met in closed session to consider matters relating to the resolution of thrift institutions.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by Chairman L. William Seidman, and Director T. Timothy Ryan, Jr. (Director of the Office of Thrift Supervision), 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)(8), (c)(9)(A)(ii) and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552B).

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

Dated: May 9, 1990.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Executive Secretary.

[FR Doc. 90–11168 Filed 5–9–90; 8:45 am]

BILLING CODE 6714–01–M

STATE JUSTICE INSTITUTE

TIME AND DATE: 9:00 a.m. to 3:00 p.m., May 18, 1990.

PLACE: Hilton Palacio del Rio, 200 South Alamo Street, San Antonio, Texas 78205

STATUS: The meeting will be open to the public, except for personnel matters.

MATTERS TO BE CONSIDERED:

Portions Open to the Public

Consideration of concept papers and applications submitted for funding.

Portions Closed to the Public

Discussion of internal personnel matters.

CONTACT PERSON FOR MORE INFORMATION: David I. Tevelin, Executive Director, State Justice Institute, 120 South Fairfax Street, Alexandria, Virginia 22314, (703) 684–6100.

David I. Tevelin,

Executive Director.

[FR Doc. 90–11116 Filed 5–8–90; 4:21 p.m.]

BILLING CODE 6820–SC–M

Corrections

Federal Register
Vol. 55, No. 92
Friday, May 11, 1990

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.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW-FRL-3754-3]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

Correction

In proposed rule document 90-8397 beginning on page 13556, in the issue of Wednesday, April 11, 1990, make the following corrections:

1. On page 13557, in the first column, under **ADDRESSES**, in the fourth line, "(OS-205)," should read "(OS-305),".

2. On the same page, in the second column, in the second complete paragraph, in the fifth line, "are" should read "were".

3. On page 13558, in the first column, in the first complete paragraph, in the 10th line, "collecting" should read "collected".

4. On page 13560, in the first column, in the first paragraph, in the first line, "2,4-" should read "2,4-D".

5. On the same page, in the same column, in the sixth line from the bottom, "shredder" should read "shredded".

6. On the same page, in the second column, in the fourth line, "dibenzo-o-dioxins" should read "dibenzo-p-dioxins".

7. On page 13561, in the second column, in the first complete paragraph, in the third line, "ADPC&E" should read "ADPC&E's".

8. On the same page, in the third column, in the "Table 7", after the fourth entry (Chromium) insert "Cyanide".

9. On the same page, in the same column, the third heading should read *Appendix VIII Constituents Likely Present in Untreated Wastes:*

10. On page 13562, in the first column, in "Table 7", in the fifth entry, "Naphthalene" was misspelled.

11. On the same page, in the same column, in the first paragraph, in the third line, "waste" should read "wastes".

12. On the same page, in the same column, in the last paragraph, in the second line, after "spray" insert "is".

13. On the same page, in the second column, in the third line from the bottom, "worse-case" should read "worst-case".

14. On page 13563, in the second column, ninth line from the bottom, "(2,4-5, DDE)" should read "(2,4-D, DDE)".

15. On the same page, in the same column, in the fourth line from the bottom, "those" should read "these".

16. On page 13564, in the first column, in the first complete paragraph, in the fifth line, "tetrachlorophenol" was misspelled.

17. On the same page, in the second column, in the table, the seventh entry in the second column should read "0.01".

18. On the same page, in the same column, in the paragraph following the table, in the 13th line, "chlorinated" should read "Chlorinated".

19. On the same page, in the third column, in the sixth line, "PQL" should read "PQLs".

20. On the same page, in the same column, in the first complete paragraph, in the seventh line "until" was misspelled.

21. On the same page, in the same column, in the table, in the fourth line from the end "Trichlorophenol" was misspelled.

22. On the same page, in the same column, in the last paragraph, in the next to last line, after "tetrachlorodibenzo-" insert "p-".

BILLING CODE 1505-01-D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket Nos. 89-133, et al.]

Radio Broadcasting Services; Various Locations

Correction

In rule document 90-7915 beginning on page 12830 in the issue of Friday, April 6, 1990, make the following correction:

§ 73.202 [Corrected]

On page 12831, in the first page-column, in the table, under Alaska, in the third table-column, in the sixth entry, "189A" should read "269A".

BILLING CODE 1505-01-D

federal register

Friday
May 11, 1990

Part II

Department of Health and Human Services

Office of Human Development Services

Availability of FY 1990 Funds and Request for Applications; Drug Abuse Prevention Program for Runaway and Homeless Youth; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Human Development Services

[Program Announcement No. 13657-902]

Availability of FY 1990 Funds and Request for Applications: Drug Abuse Prevention Program for Runaway and Homeless Youth

AGENCY: Administration for Children, Youth and Families (ACYF), Office of Human Development Services (OHDS).

ACTION: Announcement of the availability of financial assistance and request for applications for drug abuse prevention programs for runaway and homeless youth.

SUMMARY: The Family and Youth Services Bureau of the Administration for Children, Youth and Families announces the availability of funds for competing discretionary grants for the Drug Abuse Prevention Program for Runaway and Homeless Youth. The purpose of this program is to provide improved and expanded drug abuse prevention and reduction services to runaway and homeless youth.

This announcement contains the grant application process for three priority areas: A) Comprehensive Service Projects; B) Local Community and Statewide Impact Projects; and C) Demonstration Projects for Increased Services to Minority Youth, Services to Older Homeless Youth in Transition to Independent Living Programs, and Adolescent Pregnancy Projects.

Approximately thirteen million dollars ($13,000,000) is available to support grant awards under this program announcement.

DATES: The closing date for receipt of grant applications is July 2, 1990.

ADDRESSES: Address applications to: Drug Abuse Prevention Program for Runaway and Homeless Youth, Department of Health and Human Services, Office of Human Development Services, Grants and Contracts Management Division, Room 345–F.2 Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Frank Fuentes, Director, Program Support Division, Family and Youth Services Bureau, Administration for Children, Youth and Families, P.O. Box 1182, Washington, DC 20013, (202) 245–0078.

SUPPLEMENTARY INFORMATION:

Part I. General Information

A. *Program Purpose:* Section 3511 of Public Law 100–690, the Anti-Drug Abuse Act of 1988 (Act), established the Drug Abuse Education and Prevention Program for Runaway and Homeless Youth. The specific purposes of this Program are to:

1. Provide individual, family, and group counseling to runaway youth and their families and to homeless youth for the purpose of preventing or reducing the illicit use of drugs by such youth;
2. Develop and support peer counseling programs for runaway and homeless youth related to the illicit use of drugs;
3. Develop and support community education activities related to the illicit use of drugs by runaway and homeless youth, including outreach to individual youth;
4. Provide runaway and homeless youth in rural areas with assistance (including the development of community support groups) related to the illicit use of drugs;
5. Provide information and training regarding issues related to the illicit use of drugs by runaway and homeless youth to individuals involved in providing services to these youth;
6. Support research on illicit drug use by runaway and homeless youth, the effects on such youth of drug abuse by family members, and any correlation between such use and attempts at suicide; and
7. Improve the availability and coordination of local services related to drug abuse for runaway and homeless youth.

The overall purpose of the Drug Abuse Prevention Program is to help communities address the problem of drug abuse among runaway and homeless youth through the prevention, early intervention, and reduction of drug dependency. The Office of Human Development Services will award grants to support service, coordination and demonstration activities designed to achieve the specific purposes identified in numbers 1 through 7 above. Training and research programs mentioned in #5 and #6 above are being funded separately from this announcement. While funds are available for drug treatment referral as a project component, there is no provision in the statute for the direct provision of drug treatment services.

B. *Definitions:* For the purposes of this program announcement, the following definitions apply:

(1) *Drug* means a beverage containing alcohol; a controlled substance; or a controlled substance analogue.

(2) *Illicit* means unlawful or injurious.

(3) *Community-based* means located within the community and maintained with community and consumer participation in the planning, operation, and evaluation of its programs.

(4) *Public Agency* means any State, unit of local government, combination of such States or units, or any agency, department, or instrumentality of any of the foregoing.

(5) *State* means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands (Palau).

C. *Background:* The Family and Youth Services Bureau (FYSB) within the Administration for Children, Youth and Families (ACYF) serves adolescents from a population of approximately one million runaway and homeless youth who inhabit the streets of this nation annually. The abuse of drugs has had an increasingly severe impact on this vulnerable group. In 1985, 350,000 youth (including runaway, homeless and other street youth) were arrested for drug abuse violations and other drug related offenses. Reports from shelters, which serve runaway and homeless youth under the provisions of the Runaway and Homeless Youth Act, Title III of the Juvenile Justice and Delinquency Prevention Act of 1974, Public Law 93–415, as amended, indicate a growing drug abuse problem. In 1988, 15.4 percent of the youth entering the shelters indicated a personal drug abuse problem. In addition, 16.6 percent of the youth entering the shelters reported their reason for running away as drug and/or alcohol abuse on the part of their parents. The prevalance of the problem is underscored by the fact that not only are major urban areas reporting an increase in drug use among their client population, but providers in small towns and rural communities are also finding that up to 67 percent of their clients are reporting drug abuse as a primary problem. While there are indications that the use of marijuana among this population is declining, there has been a marked increase in the use of more dangerous and addictive drugs such as cocaine and its derivative crack. There has also been an increase in the abuse of alcohol among younger adolescents. The presence of alcohol is of particular concern because it is often a "gateway" drug to more serious substance abuse.

The street life environment places runaway and homeless youth at a significant risk of involvement in the abuse of illicit drugs and the related

consequence of contracting and transmitting the AIDS virus. The youth entering the shelters today are more disturbed and more difficult to serve due to the increase in substance abuse.

Service providers are concerned about finding solutions to the problem of substance abuse among runaway and homeless youth. Existing prevention, reduction, and treatment services for this client population have been largely fragmented and inadequate. While the projects funded under ACYF's FY 1989 program announcement are beginning to address the problem of fragmentation, many communities still have unmet needs in this area.

The implementation of the Anti-Drug Abuse Act of 1988 provided, for the first time, Federal financial assistance to more thoroughly address the problem of drug abuse prevention among runaway and homeless youth. The Office of Human Development Services made the initial grant awards under Section 3511 of Public Law 100–690 during FY 1989. Under the FY 1989 program announcement, discretionary grant awards were made to 104 agencies and organizations representing 36 States, including Puerto Rico and the District of Columbia. These awards were made to support projects designed to improve or expand existing services; develop networking in rural and other areas with minimal services; develop innovative program models; and provide special services for Native American youth on or near Indian reservations and Alaska Native villages. Given the magntiude of the problem and the continuing need to support communities in their efforts to address the problem, ACYF will continue this program direction under this announcement by increasing the number of grants awarded to focus on the three priority areas contained in the FY 1989 program announcement: A. Comprehensive Service Projects; B. Local Community and Statewide Impact Projects (FY 1989, Networking Projects); and C. Demonstration Projects for Increased Services to Minority Youth, Services to Older Homeless Youth in Transition to Independent Living Programs, and Adolescent Pregnancy Projects.

As mandated by section 3511 of the Act, OHDS awarded a training and technical assistance contract. Under the contract, a prototype drug education curriculum is being development and on-site technical assistance is available to provide youth service workers with the knowledge, techniques, and skills needed to improve the drug abuse prevention services available to runaway and homeless youth.

During FY 1990, a contract will be awarded to study the incidence of illicit drug use among runaway and homeless youth, the effects on such youth of drug abuse by family members and any correlations between such use and attempts at suicide and other harmful or risk taking behavior caused or abetted by drugs. These training and research projects are not a part of this program announcement. However, grantees under this program announcement will be required to fully cooperate with both contractors.

The Office of Human Development Services seeks to expand the availability of knowledge pertaining to effective drug abuse prevention, particularly early intervention methods and service delivery systems for this hard to reach population. All applications should reflect the understanding that drug abuse prevention and reduction cannot be addressed in isolation, particularly in cases where family members, especially parents, are also users of illicit drugs. Where family members are present, their involvement is strongly encouraged as an integral part of the services provided. In addition, OHDS encourages awareness of and sensitivity to the particular needs of ethnic, racial and cultural groups in the development of drug abuse prevention services in minority communities.

The improvement and expansion of direct prevention services and the development of community resources and support for runaway and homeless youth are important activities under this program announcement. Section 3511 of the Act provides for services as well as referrals to drug treatment programs. However, drug treatment itself is not the focus of this program, and will not be supported under this announcement. (Other sections of the Anti-Drug Abuse Act of 1988 support the provision of drug treatment and rehabilitation for the homeless, the medically indigent, pregnant adolescents, and teen parents.) The lack of drug treatment programs in many areas of the country will require applicants under this announcement to develop innovative approaches to securing appropriate treatment for the runaway and homeless youth they serve. This particular type of resource development is strongly encouraged.

The Family and Youth Services Bureau entered into an Interagency Agreement with the Public Health Service, DHHS, to improve access to medical services, including drug treatment for runaway and homeless youth. The Bureau of Health Care Delivery and Assistance (BHCDA) of the Public Health Service, with funds made available under the Stewart B. McKinney Homeless Assistance Act of 1987, awarded 109 grants under the Health Care for the Homeless Program to medical centers across the country to provide primary health care, including drug abuse prevention and treatment, to homeless populations. Applicants may wish to identify individual centers and, where possible, access and coordinate with these resources. For information, contact: Mr. James Gray, BHCDA, Room 7A–22, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–2512.

For information concerning the nationwide system of Health Care for the Homeless Programs, applicants may also wish to contact the National Clearinghouse for Primary Care Information at (703) 821–8955.

The Federal government is currently supporting numerous activities to prevent substance abuse and the spread of AIDS among runaway and homeless youth. The Office of Substance Abuse Prevention (OSAP) and the National Institute on Drug Abuse (NIDA) are sources of information about projects at the local and national levels and for existing prevention materials and program curricula. The Office of Human Development Services encourages applicants to coordinate their proposed activities with projects supported by OSAP and NIDA, wherever possible and practical, to reduce potential duplication. This collaboration is especially encouraged in activities to address Purposes #3, #4, and #7 as listed in section A above. Information relating to OSAP and NIDA supported projects may be obtained by contacting:

National Clearinghouse for Alcohol and Drug Information, P.O. Box 2345, Rockville, Maryland 20852, (301) 468–2600.

Alberto Mata, Ph.D., Senior Advisor, Division of Applied Research, Community Research Branch, National Institute on Drug Abuse, Room 9A–30, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–6720.

Rebecca Ashery, Section Chief, Professional Education Section, National Institute on Drug Abuse, Room 10A–54, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–6720.

Under the Drug Abuse Prevention Program, FYSB is pursuing the necessary collaboration among Federal agencies to increase the availability of treatment services as well as the responsiveness of treatment facilities to the drug abuse

problems of runaway and homeless youth.

D. *Eligibility:* The purpose of this announcement is to fund new projects. Any State, unit of local government (or combination of units of local government), public or non-profit private agency, organization, institution, or other non-profit entity (including individuals) is eligible to apply; except that grantees currently funded under the FY 1989 Drug Abuse Prevention Program for Runaway and Homeless Youth (Program Announcement No. 13657–892) are not eligible to apply for financial assistance under this announcement. In instances where more than one agency or individual submits a joint application to coordinate activities under this announcement, one legal entity must be designated as the proposed grantee.

As required by section 3511(b) of the Act, priority will be given to applicants that have experience in providing services to runaway and homeless youth.

Non-profit applicants who have not previously received support from the Office of Human Development Services must submit proof of their non-profit status with their grant application. This can be done either by making reference to the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations or by submitting a copy of its letter from IRS (IRS Code, sections 501(c)(3) and 501(c)(6)). Non-profit applicants cannot be funded without acceptable proof of this status. Although for-profit entities may participate as sub-grantees to eligible applicants, they do not qualify as applicants under this grant announcement.

Applicants must indicate in their application a willingness to cooperate with the third party contractors funded by ACYF. The contractors will provide training and technical assistance support, conduct site visits to grantees, and conduct an incidence study.

As a condition of any grant awarded under this announcement, each applicant must certify compliance with the application requirements of section 3514(b) of the Anti-Drug Abuse Act by signing the assurance form included in the application package (see Appendix II).

E. *Applicant Share of Project Costs:* A 25 percent non-Federal share ($1 for every $3 of Federal funding), either cash or third party in-kind contributions, or a combination thereof, secured from non-Federal sources, is required of all projects. For example, an applicant who applies for $75,000 in Federal funding must provide $25,000 toward the project, with a total project cost of $100,000. The Office of Human Development Services encourages applicants to propose grantee shares which will be met in cash, as opposed to in-kind contributions. Contributions of more than 25 percent are also encouraged. Applicants which do not provide the required 25 percent share will not be considered for funding.

Part II: Priority Area Descriptions

Applicants are invited to submit proposals that respond to *one* of the following priority areas:

A. Comprehensive Service Projects

Approximately 20 to 30 grants will be awarded under this priority area to improve and/or expand existing services related to preventing or reducing the use of illicit drugs among runaway and homeless youth and their families. In addressing the families of such youth, proposals should include a methodology that considers the impact of the drug abuse problem on the immediate family, extended family and peers that compose the youth's home environment. Applicants must also demonstrate how additional resources will be utilized to expand or improve current service delivery through improved outreach, counseling (individual, family, group, and peer), intake and medical screening, referrals to treatment and the provision of aftercare services. Proposals should show evidence of joint planning with other agencies in the community towards the development of a comprehensive approach to service delivery. Where more than one agency joins to submit a single application, letters of commitment should be included as well as a clearly defined task chart showing the responsibilities and involvement of the designated agencies.

Duration: Not to exceed 24 months, with the possibility of renewal for an additional 12-month period based on the availability of funds and satisfactory performance of the grantee.

Federal Share of Project Costs: Up to $150,000 each year.

B. Local Community and Statewide Impact Projects

Approximately 20 to 30 grants will be awarded under this priority area to address the issues of (1) improved local community-based networking and (2) effective Statewide drug abuse prevention programming for runaway and homeless youth.

1. Local Community Impact Projects

The Office of Human Development Services encourages the development of community support and resources to ensure the provision of quality, coordinated drug abuse prevention and reduction efforts in rural areas and in communities with fragmented or minimal services for runaway and homeless youth. Runaway and homeless youth, as well as service providers, often cite the lack of coordinated community-based services, information resources and difficulty in obtaining treatment services as reasons for sustained illicit drug use. This sub-area encourages the creation of community resource development efforts to address the need for community education, the coordination of existing services for runaway and homeless youth and their families, and the creation of community support groups that specifically address the issue of drug abuse among runaway and homeless youth. Applications should identify current barriers to coordinated services, the continuum of care, and the establishment of successful networks and should propose alternatives to address these barriers. Examples of alternatives which might be unertaken by these networks include the adjustment of priorities among other related service providers, expanded use of the media, promulgation of information in languages and customs indigenous of ethnic communities, and greater use of community forums. Applications should also clearly demonstrate a model of improved service delivery as a result of the better coordination of resources. Proposals must show clear evidence of joint planning and defined responsibilities. Applicants must establish a network of providers, with letters of commitment from each, and should propose innovative models for successfully developing and implementing a network of services that can be replicated in other communities. Uniform case management practices among all providers is an example of effective networking as are innovative combinations of services, particularly in geographic areas with minimal resources for runaway and homeless youth.

2. State Impact Projects

There is a need to establish more Statewide networking and program coordination efforts in support of runaway and homeless youth drug abuse prevention services. The Office of Human Development Services *seeks to provide grants for this purpose in States that do not currently have Statewide organizations in support of runaway and homeless youth services.* Applicants proposing State impact projects must

demonstrate their capacity to conduct Statewide networking efforts and must show evidence that they have broad based support from organizations working with or on behalf of runaway and homeless youth.

The Office of Human Development Services will consider projects to enable organizations to expand the existing body of knowledge and/or projects designed to generate additional financial, service or other resources to address runaway and homeless youth drug abuse prevention efforts Statewide. To be considered for a State impact grant, the applying organization must have the capacity to undertake projects that are Statewide in magnitude.

Examples of the types of projects to be conducted under this sub-area include, but are not limited to:

- Projects for Statewide public education campaigns aimed at promoting awareness of runaway and homeless drug abusing youth and their needs. Applications should identify the methods to be used to organize and implement the campaign.
- Projects designed to collect and disseminate Statewide data in support of runaway and homeless youth programming at the State level.
- Projects conducting Statewide assessments of existing service systems and defining what can and should be done to improve them.
- Projects that develop and implement Statewide strategies to increase coordination and networking among runaway and homeless youth service providers who are dealing with youth with drug abuse problems.
- Projects that build the capacity of organizations to identify and compete for existing local, State and Federal drug abuse funds to increase services to runaway and homeless youth.
- Projects to assist organizations in gathering data on a Statewide basis on the incidence of drug abuse and the types of drugs involved.

Applicants must clearly indicate in Box 11 of the 424 form which sub-area (i.e., B.1 or B.2) is being addressed in their application.

Duration: Local Community Impact Projects will not exceed 24 months, with the possibility of renewal for an additional 12-month period based on the availability of funds and satisfactory performance of the grantee. State Impact Projects will not exceed 17 months, with the possibility of renewal for an additional 12 month period based on the availability of funds and satisfactory performance of the grantee.

Federal Share of Project Costs: Local Community Impact Project awards will not exceed $150,000 each 12 month period. Grant awards for State Impact Projects will not exceed $50,000 for the 17 month period. The Local Community Impact Projects will support networking activities for the actual delivery of services, while the State Impact Projects will focus on organizing and data gathering activities, hence the difference in the funding levels.

C. Demonstration Projects for Increased Services to Minority Youth, Services to Older Homeless Youth in Transition to Independent Living Programs, and Adolescent Pregnancy Projects

Approximately 10 to 20 grants will be awarded under this priority area to support the development of model approaches for addressing the prevention and reduction of illicit drug use by (1) minority runaway and homeless youth; (2) homeless youth preparing to enter independent living arrangements; and (3) pregnant adolescents among runaway and homeless youth.

The Office of Human Development Services is interested in funding programs in this priority area that have potential for replication or that would add to the existing knowledge base. Therefore, all applications must include a plan for evaluating outcomes and developing appropriate materials which can be widely disseminated.

Under this priority area all applicants must demonstrate collaboration with appropriate agencies and organizations in the conduct of their projects. Applicants should list all organizations that will work on the project and describe their contributions.

1. Minority Youth Projects

Many communities do not have an adequate system for serving runaway and homeless minority youth who are at exceptionally high risk of involvement with illicit drugs. This may be due to a lack of culturally relevant services, inadequate coordination or ineffective outreach. These youth typically come from disadvantaged neighborhoods and/or dysfunctional family environments, have unmet basic needs, health and social problems, and inadequate role models and positive support systems. For many of these youth family reunification is not possible. The Office of Human Development Services is interested in supporting programs that have formal linkages between youth-serving minority organizations and organizations serving runaway and homeless youth and would offer innovative ways to expand and improve services to these youth.

Examples of the types of projects to be conducted under this sub-area may include, but are not limited to:

- Projects which develop innovative outreach and referral approaches to treatment programs which overcome the barriers to treatment often experienced by minority youth such as race, language, and ability to pay for services.
- Projects which develop and demonstrate specific methods for increasing runaway and homeless minority youth access and participation in drug abuse education and prevention programs.
- Projects which develop and implement comprehensive drug-related services and programs which address the specific cultural needs of minority youth.
- Projects which actively involve and educate the parents of minority youth who are receiving runaway and homeless youth drug prevention services.
- Projects designed to promote drug-free lifestyles for minority youth through better outreach, comprehensive assessments and appropriate referrals.
- Projects involving collaborative programming for the provision of comprehensive drug-related support services for minority youth.

2. Innovative Drug Prevention Projects for Older Homeless Youth in Transition to Independent Living Arrangements

For many homeless youth, family reunification is not possible. This problem is compounded by the fact that many of these youth cannot live in a safe environment with a relative and have no other safe living arrangements available to them. The Office of Human Development Services is implementing a new national grant program (under a separate **Federal Register** announcement) to establish and expand transitional living projects for homeless youth who need assistance in making the transition from a homeless lifestyle to one of an independent, fully functioning adult. This youth population has many social problems and their access to needed services is limited. Given the nature of their homeless lifestyle, these youth are at high risk of involvement with illicit drugs. Since operation of this new program is imminent, this sub-area is not intended for programs serving youth living in group homes, foster care, or other stable living environments.

To facilitate the service providers' efforts to help these youth make successful transitions to independent living arrangements, OHDS is interested in funding applications which describe

model approaches to early drug abuse identification, counseling and related support services, and referrals to appropriate treatment services. Applications must contain written letters or other assurances that the project will be conducted in collaboration with transition to independent living programs for homeless youth and other appropriate organizations such as drug and rehabilitation programs.

Examples of the types of projects to be conducted under this priority area include, but are not limited to:

- Models of agency collaboration with drug treatment programs for the provision of drug abuse prevention and treatment services for homeless youth preparing for independent living. The Office of Human Development Services is particularly interested in programs which address the youths' drug abuse problem while, at the same time, maintaining them in a transitional living program.
- Projects focused on the early identification of drug abuse problems and the provision of appropriate pre-treatment services for youth making the transition to independent living.
- Projects designed to provide drug abuse education to youth who are making transitions to independent living arrangements.
- Projects using cost effective methods for the early identification of drug abuse and the provision of appropriate comprehensive services which meet the needs of youth making the transition to independent living.

3. Adolescent Pregnancy Projects

The Office of Human Development Services is concerned about runaway and homeless adolescent females who are pregnant and at high risk of abusing drugs and receiving little or no prenatal or postnatal health care. Of particular concern is the growing incidence of premature and full term infants suffering from illnesses ranging from low-birth weight and its attendant complications to drug addiction and withdrawal as a consequence of the mother's substance abuse during pregnancy.

In the case of homeless and runaway adolescent females, the absence of a stable home environment all but eliminates the likelihood of their receiving vital health care during pregnancy. When compounded by substance abuse, the consequence is often complicated child births, drug-addicted newborns and, sometimes, abandonment of the infant by the mother. This situation is increasingly taxing the health care and social service delivery systems and contributing to the cycle of family dysfunction and separation.

The Office of Human Development Services is interested in supporting projects which demonstrate effective ways of addressing this critical problem through the provision of targeted outreach and supportive services for these adolescents. By supporting projects which address this issue, OHDS hopes to reduce the number of runaway and homeless adolescent females who are unable to secure adequate medical care for themselves during pregnancy and for their children after their birth. The effectiveness of these programs will be enhanced by emphasizing strong community linkages and cooperative efforts among appropriate service providers.

Examples of the type of projects OHDS is interested in supporting include, but are not limited to:

- Programs which focus on the early identification of drug abusing adolescent females among the runaway and homeless youth population and the provision of pregnancy prevention and prenatal education, prenatal and post-natal health care appropriate referrals for drug treatment services.
- Programs which improve coordination and linkages between local runaway and homeless youth service providers and health and drug treatment programs so that the medical needs of this target population are better served.
- Outreach and intervention programs which use responsible community volunteers to identify these high risk youth, assist them in securing pre- and postnatal service, and are willing to maintain supportive contact with such youth during their early parenting years.
- Programs that focus on serving youth who are considered hard to reach due to cultural differences, geographic isolation or other factors.
- Programs designed to bring responsible senior volunteers and high-risk adolescent youth together in mutually supportive roles.
- Programs designed to reduce and eliminate barriers to medical services, such as legal and financial considerations, so that these youth receive the level of medical care necessary to reduce complications during delivery and produce healthy drug-free babies.
- Prevention programs responding to the primary health and drug education needs of this population so that they are able to acquire the life skills necessary for successful living.

Applicants applying for assistance under priority area C must set aside up to 10 percent of their budget, but not less than $10,000, to have an independent evaluation conducted of their program. This evaluation must be conducted by a third party evaluator(s) selected by the applicant. The third party evaluator must assess the accomplishments of the applicant's program and service delivery models. The evaluator will collect data from the applicant and other relevant sources to analyze at a minimum (a) the progress and effectiveness of the project in meeting its intended demonstration goals and objectives; (b) the problems inherent to the service delivery model; (c) the potential for replication of the model; (d) the number and types of youth who were served or could be served by program expansion/replication; and (e) alternative approaches to the dissemination of materials that would facilitate program replication.

The Office of Human Development Services invites the identification of additional issues, to be addressed under the evaluation, which need further development for the effective prevention, intervention and reduction of drug abuse among runaway and homeless youth. Applicants must clearly indicate in Box 11 of the 424 form which of the three sub-areas (i.e., C.1, C.2 or C.3.) is being addressed in their application.

Duration: Not to exceed 17 months, with the possibility of renewal for an additional 12-month period based on the availability of funds and satisfactory performance of the grantee.

Federal Share of Project Costs Up to $212,500 for the initial 17 month period.

Part III: Criteria for Review and Evaluation of Applications

An application must meet all of the eligibility requirements specific to the priority area under which it is being submitted. This includes eligibility of the applicant, duration of the project, 25 percent minimum applicant share, and responsiveness to the purpose of the priority area.

Applications which meet these eligibility requirements will be evaluated by a panel of experts knowledgeable about issues related to runaway and homeless youth and illicit drug use who will comment on and score the applications based on the four criteria listed below.

To ensure the maximum score for each criterion, it is imperative that the program narrative section of the application clearly address each of these four areas. These criteria also incorporate the statutory review criteria

in section 3515(a) of the Anti-Drug Abuse Act.

A. Objectives and Need for Assistance: (20 points)

• Identify the specific purpose(s) of section 3511 of the Anti-Drug Abuse Act that is being addressed by the proposal.

• Pinpoint any relevant physical, economic, social, financial, institutional, or other problems requiring a solution (including the need for additional services for addressing the illicit use of drugs by runaway and homeless youth) in the geographic area(s) that the project is proposed to serve. (Section 3515(a)(5))

• Give the precise location of the project and area(s) to be served by the proposed project (maps or other graphic aids may be attached). Provide a detailed description of the emerging or current status of illicit drug use among runaway and homeless youth and their families in the proposed target area. (Section 3515(a)(2))

• Demonstrate the need for the project and state the principal and subordinate objectives of the project. Supporting documentation or testimonies from concerned interests other than the applicant may be used.

• Describe the innovativeness of the project, i.e., how it incorporates new or innovative techniques; how it builds upon the delivery of existing drug abuse services; how it will expand or improve existing services; and the anticipated impact of this effort on the total range of services provided to runaway and homeless youth.

B. Results or Benefits Expected: (25 points)

• Identify the results and benefits to be derived from the project, especially any increases in the applicant's capacity to provide services to address the illicit use of drugs by runaway and homeless youth; and the extent to which the project will increase the level of services, or will coordinate with other services, in the community.

• Describe any anticipated changes in policy and/or practice among public and private service providers that will result in improved service delivery (e.g., identify any manuals, training curricula or reports, proposed as a project accomplishment).

• Provide justification for the relative cost of the project in relation to its anticipated effectiveness in carrying out the purposes of section 3511 of the Anti-Drug Abuse Act.

C. *Approach:* (35 points)

• Outline a plan of action pertaining to the scope of the project and detail how the proposed work will be accomplished. Cite factors which might accelerate or decelerate the work and your reasons for taking this approach as opposed to others.

• Provide a description of the proposed project, including the activities for accomplishing intervention, prevention, education, client involvement, treatment referral, outreach efforts, and coordination with other agencies.

• Describe any unusual features of the project, such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvements (e.g., how project will be maintained after termination of Federal support).

• List the activities to be carried out in chronological order to show the schedule of accomplishments and their target dates (GANTT or PERT charts may be used for this purpose).

• List each organization, cooperator, consultant, or other key individuals who will work on the project (including the lead agency) along with a short description of the nature of their effort or contribution. In the case of an application submitted by more than one agency, describe the lead agency's role and method for coordinating activities; and the role and responsibility of each member agency. Letters of commitment that show evidence of a joint planning and implementation role in the project must be included. Letters of commitement from appropriate service delivery agencies and community and political organizations that express potential involvement may also be attached.

• Describe the relationship between this project and other work planned, anticipated, or underway with Federal assistance.

• Identify the kinds of data to be collected and maintained, and discuss the criteria to be used to evaluate the results and success of the project. Explain the methodology that will be used to determine if the needs identified and discussed are being met and if the results and benefits identified are being achieved. Provide quantitative projections of the accomplishments to be achieved, if possible.

D. *Staff Background and Experience:* (20 points)

• Present a biographical sketch of the proposed program director with the following information: name, address, telephone number, background, and other qualifying experience for the project.

• List the name, training and background for other proposed key personnel.

• Provide a brief description of the applicant's organizational experience in providing services to runaway and homeless youth. In the case of an application submitted by an individual, demonstrate that a strong connection exists between the individual and community-based agencies or services, and that the individual will have ongoing access to the service population. [Section 3511(b)]

Part IV: The Application Process

A. *Availability of Forms:* All of the forms and instructions needed for submitting an application under this announcement are included in Appendix I. Single sided copies of these forms should be reproduced and used to prepare the application package.

A complete application consists of:

(1) Standard Form 424: Application for Federal Assistance;

(2) Standard Form 424A: Budget Information;

(3) Assurances

(a) Standard Form 424B: Non-Construction Programs;

(b) Drug-Free Workplace Certification;

(c) Debarment Certification;

(d) Certification Regarding Lobbying; and

(e) The Anti-Drug Abuse Act of 1988 Certification.

(4) Program Narrative: A narrative description of the project, organized under the headings which address the four evaluation criteria identified in Part III: (A) Objectives and Need for Assistance; (B) Results or Benefits Expected; (C) Approach;' and (D) Staff Background and Experience.

The program narrative must be typed, double-spaced, on 8½ x 11 inch bond paper. All pages of the narrative (included charts, tables, and maps) must be suquentially numbered, beginning with the "Objective and Need for Assistance" section as page number one. The program narrative must not exceed 25 double-spaced pages.

(5) Project Abstract: A brief (approximately 100 word) description of the project, typed on 8½ x 11 inch bond paper.

(6) Appendices/Attachments: Letters of support, exhibits, and other supporting documents must not exceed ten pages.

B. *Application Submission:* Each application must be signed by an official authorized to act on behalf of the applicant agency, organization, institution, or other entity and to assume responsibility for the obligations imposed by the terms and conditions of any grant awarded.

Applications must be prepared in accordance with the guidance provided in this announcement and the

instructions in the attached application package.

One signed original and two copies of the application, including all attachments, are required.

The priority area (see Part II of this announcement) under which the application is being submitted must be clearly identified in Block 11 of Standard Form 424.

Completed applications must be sent to: Drug Abuse Prevention Program for Runaway and Homeless Youth, Department of Health and Human Services, Office of Human Development Services, Grants and Contracts Management Division, Room 345–F Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Hand delivered applications will be accepted at the OHDS Grants and Contracts Management Division Office during the normal working hours of 8:30 a.m. to 5 p.m., Monday through Friday.

C. *Closing Date for the Submission of Applications:* The closing date for receipt of applications under this announcement is July 2, 1990.

1. *Deadlines.* Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date at the address specified in the application submission section of this announcement; or

b. Sent on or before the deadline date and received in time for the independent review under Chapter 1–62 of the *HHS Grants Administration Manual.* Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

2. *Late Applications.* Applications which do not meet the criteria in the above paragraphs are considered late applications. The granting agency will notify each late applicant that its application will not be considered in the current competition.

3. *Extension of Deadline.* The Administration for Children, Youth and Families may extend the deadline for all applicants because of acts of God such as floods, hurricanes, etc. or when there is widespread disruption of the mail. However, if the granting agency does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicant.

D. *Screening of Applications:* All applications will be initially screened to determine conformance with the following requirements:

(1) Deadline for submittal;
(2) Appropriate number of pages;
(3) Identification of priority area;
(4) Signature of authorizing official; and
(5) Federal funding requests not exceeding the limitations set by the priority area.

These preliminary screening requirements will be rigorously enforced. Applications which do not meet these requirements will not be considered in the competition and the applicant will be so informed.

E. *Application Consideration:* Each application will be reviewed and scored against the criteria outlined in Part III of this announcement and its responsiveness to the minimum requirements identified in Part II. The review will be conducted in Washington, DC. Reviewers will be persons knowledgeable about issues relating to runaway and homeless youth and illicit drug use.

The results of the competitive review will be analyzed by Federal staff and will be the primary factor taken into consideration by the Associate Commissioner, Family and Youth Services Bureau who, in consultation with OHDS Regional officials, will recommend to the Commissioner of ACYF programs to be funded. The Commissioner of ACYF will make the final selections. Applications may be funded in whole or in part. Consideration will also be given to ensuring that a variety of geographic areas are served, that projects with different auspices are selected, and that a variety of project designs and models are represented.

Successful applicants will be notified through the issuance of a Financial Assistance Award. The award will state the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the grant award, the effective date of the grant, the total project period, the budget period, and the amount of the non-Federal matching share.

Organizations whose applications have been disapproved will be notified in writing by the Commissioner of the Administration for Children, Youth and Families.

F. *Paperwork Reduction Act of 1980:* Under the Paperwork Reduction Act of 1980, Public Law 96–511, the Department is required to submit to the Office of Management and Budget (OMB) for review and approval any reporting and recordkeeping requirements and regulations, including program announcements. This program announcement does not contain information collection requirements beyond those approved by OMB.

G. *Executive Order 12372—Notification Process:* This program is covered under Executive Order (E.O.) 12372, "Intergovernmental Review of Federal Programs," and 45 CFR Part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs. All States and territories except Alaska, Idaho, Kansas, Louisiana, Minnesota, Nebraska, Virginia, American Samoa, and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). (See attached list of the Single Points of Contact for each State and Territory included in Appendix II of this announcement.) Applicants from these nine areas need take no action regarding E.O. 12372. Applications for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372.

Other applicants should contact their SPOC as soon as possible to alert them of the perspective application and receive any necessary instructions. Applicants must submit any required material to the SPOC as early as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or date of contact if no submittal is required) on the SF 424, Block 16a. OHDS will notify the State of any applicant who fails to indicate SPOC contact (when required) on the application form.

SPOCs have 60 days from the grant application deadline date to comment on applications for financial assistance under this program. SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to differentiate clearly between mere advisory comments and those official State process recommendations which they intend to trigger the "accommodate or explain" rule.

When comments are submitted directly to OHDS, they should be addressed to: Drug Abuse Prevention Program for Runaway and Homeless

Youth, Department of Health and Human Services, Office of Human Development Services, Grants and Contracts Management Division, Room 345–F Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Catalog of Federal Domestic Assistance Program Number 13.657, Drug Abuse Education and Prevention Program for Runaway and Homeless Youth)

Dated: April 25, 1990.

Wade Horn,

Commissioner, Administration for Children, Youth and Families.

Approved: May 3, 1990.

Mary Sheila Gall,

Assistant Secretary for Human Development Services.

Assurances Required by Section 3514 of the Anti-Drug Abuse Act of 1988

The grantee certifies that, as a condition of the grant, the agency, organization, or individual will meet the following statutory requirements:

(1) provide that such project or activity shall be administered by or under the supervision of the applicant;

(2) provide for the proper and efficient administration of such project or activity;

(3) provide that regular reports on such project or activity shall be submitted to the Office of Human Development Services; and

(4) provide such fiscal control and fund accounting procedures as may be necessary to ensure prudent use, proper disbursement, and accurate accounting of funds received under this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

BILLING CODE 4130-01-M

APPENDIX I

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

1. TYPE OF SUBMISSION: *Application* ☐ Construction ☐ Non-Construction; *Preapplication* ☐ Construction ☐ Non-Construction	2. DATE SUBMITTED	Applicant Identifier
	3. DATE RECEIVED BY STATE	State Application Identifier
	4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address (*give city, county, state, and zip code*):	Name and telephone number of the person to be contacted on matters involving this application (*give area code*)

6. EMPLOYER IDENTIFICATION NUMBER (EIN): ☐☐ – ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: (*enter appropriate letter in box*) ☐

A. State — H. Independent School Dist.
B. County — I. State Controlled Institution of Higher Learning
C. Municipal — J. Private University
D. Township — K. Indian Tribe
E. Interstate — L. Individual
F. Intermunicipal — M. Profit Organization
G. Special District — N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other (*specify*):

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐ ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT (*cities, counties, states, etc.*):

13. PROPOSED PROJECT: Start Date	Ending Date	14. CONGRESSIONAL DISTRICTS OF: a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON

DATE _____

b. NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item: Entry:

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. if more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

Item: Entry:

12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

OMB Approval No. 0348-0044

BUDGET INFORMATION — Non-Construction Programs

SECTION A – BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$
2.						
3.						
4.						
5. TOTALS		$	$	$	$	$

SECTION B – BUDGET CATEGORIES

6 Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY (1)	(2)	(3)	(4)	Total (5)
a. Personnel	$	$	$	$	$
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges (sum of 6a - 6h)					
j. Indirect Charges					
k. TOTALS (sum of 6i and 6j)	$	$	$	$	$
7. Program Income	$	$	$	$	$

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Standard Form 424A (4-88)
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SECTION C - NON-FEDERAL RESOURCES

(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$
9.				
10.				
11.				
12. TOTALS (sum of lines 8 and 11)	$	$	$	$

SECTION D - FORECASTED CASH NEEDS

	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$	$	$	$	$
14. NonFederal					
15. TOTAL (sum of lines 13 and 14)	$	$	$	$	$

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT

(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTALS (sum of lines 16 -19)	$	$	$	$

SECTION F - OTHER BUDGET INFORMATION

(Attach additional Sheets if Necessary)

21. Direct Charges:	22. Indirect Charges:
23. Remarks	

SF 424A (4-88) Page 2
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INSTRUCTIONS FOR THE SF-424A

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A,B,C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A,B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

Section A. Budget Summary
Lines 1-4, Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the catalog program title and the catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in *Column* (a) and the respective catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) through (g.)

For new applications, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

Lines 1-4, Columns (c) through (g.) (continued)

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 — Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Lines 6a-i — Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

INSTRUCTIONS FOR THE SF-424A *(continued)*

Line 7 – Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal-Resources

Lines 8-11 – Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) – Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b) – Enter the contribution to be made by the applicant.

Column (c) – Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d) – Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e) – Enter totals of Columns (b), (c), and (d).

Line 12 — Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 – Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 – Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 – Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16 - 19 – Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 – Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 – Use this space to explain amounts for individual direct object-class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 – Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 – Provide any other explanations or comments deemed necessary.

OMB Approval No. 0348-0040

ASSURANCES — NON-CONSTRUCTION PROGRAMS

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.
9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program andto purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

BILLING CODE 4150-01-C

SF 424B (4-88) Back

U.S. Department of Health and Human Services Certification Regarding Drug-Free Workplace Requirements Grantees Other Than Individuals

By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

This certification is required by regulations implementing the Drug-Free Workplace Act of 1988, 45 CFR part 76, subpart F. The regulations, published in the January 31, 1989 **Federal Register**, require certification by grantees that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when HHS determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment.

The grantee certifies that it will provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing a drug-free awareness program to inform employees about:

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and,

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will:

(1) Abide by the terms of the statement; and,

(2) Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;

(e) Notifying the agency within ten days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction;

(f) Taking one of the following actions, within 30 days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

(1) Taking appropriate personnel action against such an employee, up to and including termination; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

By signing and submitting this proposal, the applicant, defined as the primary participant in accordance with 45 CFR part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal Department or agency;

(b) have not within a 3-year period preceding, this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) are not presently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1) (b) of this certification; and

(d) have not within a 3-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

The inability of a person to provide the certification required above will not necessarily result in denial of participation in this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the Department of Health and Human Services (HHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

The prospective primary participant agrees that by submitting this proposal, it will include the clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transaction." provided below without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions

(To Be Supplied to Lower Tier Participants)

By signing and submitting this lower tier proposal, the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.

(b) where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal.

The prospective lower tier participant further agrees by submitting this proposal that it will include this clause entitled "certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Coverd Transactions. "without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Certification Regarding Lobbying

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Organization

Authorized Signature Title Date

Note: If Disclosure Forms are required, please contact: Mr. William Sexton, Deputy Director, Grants and Contracts Management Division, Room 341F, HHH Building, 200

Independence Avenue SW, Washington, D.C. 20201–0001.

Appendix II—Executive Order 12372—State Single Points of Contact

Alabama
Mrs. Moncell Thornell
State Single Point of Contact
Alabama Department of Economic and Community Affairs
3465 Norman Bridge Road
Post Office Box 250347
Montgomery, Alabama 36125–0347
Tel. (205) 284–8905

Alaska
None

Arizona
Mrs. Janice Dunn
ATTN: Arizona State Clearinghouse
1700 West Washington, Fourth Floor
Phoenix, Arizona 85007
Tel. (602) 542–5004

Arkansas
Mr. Joseph Gillesbie, Manager
State Clearinghouse
Office of Intergovernmental Services
Department of Finance and Administration
P.O. Box 3278
Little Rock, Arkansas 72203
Tel. (501) 371–1074

California
Loreen McMahon, Grants Coordinator
Office of Planning and Research
1400 Tenth Street
Sacramento, California 95814
Tel. (916) 445–0613

Colorado
State Single Point of Contact
State Clearinghouse
Division of Local Government
1313 Sherman Street, Room 520
Denver, Colorado 80203
Tel. (303) 866–2156

Connecticut
Under Secretary
ATTN: Intergovernmental Review Coordinator
Comprehensive Planning Division
Office of Policy and Management
80 Washington Street
Hartford, Connecticut 06106–4459
Tel. (203) 566–3410

Delaware
Francine Booth
State Single Point of Contact
Executive Department
Thomas Collins Building
Dover, Delaware 19903
Tel. (302) 736–3326

District of Columbia
Lovetta Davis
State Single Point of Contact
Executive Office of the Mayor
Office of Intergovernmental Relations
Room 416, District Building
1350 Pennsylvania Avenue NW.
Washington, D.C. 20004
Tel. (202) 727–9111

Florida
Karen McFarland
Director of Intergovernmental Coordination
Single Point of Contact
Executive Office of the Governor
Office of Planning and Budgeting
The Capitol
Tallahassee, Florida 32399–0001
Tel. (904) 488–8114

Georgia
Charles H. Badger, Administrator
Georgia State Clearinghouse
270 Washington Street SW.
Atlanta, Georgia 30334
Tel. (404) 656–3855

Hawaii
Harold S. Masumoto
Acting Director
Office of State Planning
Department of Planning and Economic Development
Office of the Governor
State Capitol
Honolulu, Hawaii 96813
Tel. (808) 548–3016 or 548–3085

Idaho
None

Illinois
Tom Berkshire
State Single Point of Contact
Office of the Governor
State of Illinois
Springfield, Illinois 62706
Tel. (217) 782–8639

Indiana
Frank Sullivan
Budget Director
State Budget Agency
212 State House
Indianapolis, Indiana 46204
Tel. (317) 232–5610

Iowa
Steven R. McCann
Division of Community Progress
Iowa Department of Economic Development
200 East Grand Avenue
Des Moines, Iowa 50309
Tel. (515) 281–3725

Kansas
None

Kentucky
Robert Leonard
State Single Point of Contact
Kentucky State Clearinghouse
2nd Floor, Capital Plaza Tower
Frankfort, Kentucky 40601
Tel. (502) 564–2382

Maine
State Single Point of Contact
ATTN: Joyce Benson
State Planning Office
State House Station #38
Augusta, Maine 04333
Tel. (207) 289–3261

Maryland
Mary Abrams
Director
Maryland State Clearinghouse
Department of State Planning
301 West Preston Street
Baltimore, Maryland 21201–2365
Tel. (301) 225–4490

Massachusetts
State Single Point of Contact
ATTN: Beverly Boyle
Executive Office of Communities and Development
100 Cambridge Street, Room 904
Boston, Massachusetts 02202
Tel. (617) 727–3253

Michigan
Michelyn Pasteur
Deputy Director, Local Development Services
Department of Commerce
P.O. Box 30225
Lansing, Michigan 48903
Tel. (517) 375–1838
Note: Please direct correspondence to: Manager, Federal Project Review System, 6500 Mercantile Way, Suite 2, Lansing, Michigan 48911 Tel. (517) 334–6190

Minnesota
None

Mississippi
Cathy Mallette
Clearinghouse Officer
Department of Finance and Administration
421 West Pascagoula Street
Jackson, Mississippi 39206
Tel. (601) 960–4282

Missouri
Lois Pohl
Federal Assistance Clearinghouse
Office of Administration
Division of General Services
P.O. Box 809
Room 430, Truman Building
Jefferson City, Missouri 65102
Tel. (314) 751–4834

Montana
Deborah Davis
State Single Point of Contact
Intergovernmental Review Clearinghouse
c/o Office of Lieutenant Governor
Capitol Station
Room 210—State Capitol
Helena, Montana 59620
Tel. (406) 444–5522

Nebraska
None

Nevada
Nevada Office of Community Services
Capitol Complex
Carson City, Nevada 89710
Tel. (702) 885–4420
NOTE: Please direct correspondence and questions to: John Walker, Clearinghouse Coordinator, Tel. (702) 885–4420

New Hampshire
Robert W. Varney
Director
New Hampshire Office of State Planning
Attn: Intergovernmental Review Process/ James E. Bieber
2½ Beacon Street
Concord, New Hampshire 03301
Tel. (603) 271–2155

New Jersey
Mr. Barry Skokowski, Director
Director
Division of Local Government Services
Department of Community Affairs, CN 803
Trenton, New Jersey 08625–0803
Tel. (609) 292–6613
Note: Please direct correspondence and questions to: Nelson S. Silver, State Review Process, Division of Local Government Services, CN 803, Trenton, New Jersey 08625–0803, Tel. (609) 292–9025

New Mexico
Dean Olson, Director
Management & Program Analysis Division
Department of Finance & Administration
Room 424, State Capitol Building
Santa Fe, New Mexico 87503
Tel. (505) 827–3885

New York
New York State Clearinghouse
Division of the Budget
State Capitol
Albany, New York 12224
Tel. (518) 474–1605

North Carolina
Mrs. Chrys Baggett
Director
Intergovernmental Relations
N.C. Department of Administration, 116 W. Jones Street
Raleigh, North Carolina 27611
Telephone (919) 733–0499

North Dakota
William Robinson
State Single Point of Contact
Office of Intergovernmental Affairs
Office of Management and Budget
14th Floor, State Capitol
Bismarck, North Dakota 58505
Tel. (701) 224–2094

Ohio
Larry Weaver
State Single Point of Contact
State/Federal Funds Coordinator
State Clearinghouse
Office of Budget and Management
30 East Broad Street, 34th Floor
Columbus, Ohio 43266–0411
Tel. (614) 466–0698

Oklahoma
Don Strain
State Single Point of Contact
Oklahoma Department of Commerce
Office of Federal Assistance Management
6601 Broadway Extension
Oklahoma City, Oklahoma 73116
Tel. (405) 843–9770

Oregon
Attn: Delores Streeter
State Single Point of Contact
Intergovernmental Relations Division
State Clearinghouse
155 Cottage Street N.E.
Salem, Oregon 97310
Tel. (503) 373–1998

Pennsylvania
Pennsylvania Intergovernmental Council
P.O. Box 11880
Harrisburg, Pennsylvania 17108
Tel. (717) 783–3700

Rhode Island
Daniel W. Varin
Associate Director
Statewide Planning Program
Department of Administration
Division of Planning
265 Melrose Street
Providence, Rhode Island 02907
Tel. (401) 277–2656
NOTE: Please direct correspondence and questions to: Review Coordinator, Office of Strategic Planning

South Carolina
Danny L. Cromer
State Single Point of Contact
Grant Services
Office of the Governor
1205 Pendleton Street, Room 477
Columbia, South Carolina 29201
Tel. (803) 734–0435

South Dakota
Susan Comer
State Clearinghouse Coordinator
Office of the Governor
500 East Capitol
Pierre, South Dakota 57501
Tel. (605) 773–3212

Tennessee
Charles Brown
State Single Point of Contact
State Planning Office
500 Charlotte Avenue
309 John Sevier Building
Nashville, Tennessee 37219
Tel. (615) 741–1676

Texas
Ralph Boeker, Jr.
Office of Budget and Planning
Office of the Governor
P.O. Box 12428
Austin, Texas 78711
Tel. (512) 463–1778

Utah
Dale Hatch
Director, Office of Planning and Budget
State of Utah
116 State Capitol Building
Salt Lake City, Utah 84114
Tel. (801) 533–5245

Vermont
Bernard D. Johnson
Assistant Director
Office of Policy Research & Coordination
Pavilion Office Building
109 State Street
Montpelier, Vermont 05602
Tel. (802) 828–3326

Virginia
None

Washington
Catherine Townley, Coordinator
Intergovernmental Review Process
Department of Community Development
9th and Columbia Building
Olympia, Washington 98504–4151
Tel. (206) 753–4978

West Virginia
Mr. Fred Cutlip, Director
Community Development Division
Governor's Office of Community and Industrial Development
Building #6, Room 553
Charleston, West Virginia 25305
Tel. (304) 348–4010

Wisconsin
James R. Klauser, Secretary
Wisconsin Department of Administration
101 South Webster Street, GEF 2
P.O. Box 7864
Madison, Wisconsin 53707–7864
Tel. (608) 266–1741
Note: Please direct correspondence and question to: Thomas Krauskopf, Federal-State Relations Coordinator, Wisconsin Department of Administration

Wyoming
Ann Redman
State Single Point of Contact
Wyoming State Clearinghouse
State Planning Coordinator's Office
Capitol Building
Cheyenne, Wyoming 82002
Tel. (307) 777–7574

American Samoa
None

Guam
Michael J. Reidy
Director
Bureau of Budget and Management Research
Office of the Governor
P.O. Box 2950
Agana, Guam 96910
Tel. (671) 472–2285

Northern Mariana Islands
State Single Point of Contact
Planning and Budget Office
Office of the Governor
Saipan, CM
Northern Mariana Islands 96950

Palau
None

Puerto Rico
Patria Custodio/Israel Soto Marrero
Chairman/Director
Puerto Rico Planning Board
Minillas Government Center
P.O. Box 41119
San Juan, Puerto Rico 00940–9985
Tel. (809) 727–4444

Virgin Islands
Jose L. George, Director
Office of Management and Budget
No. 32 & 33 Kongens Gade
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Tel. (809) 774–0750

[FR. Doc. 90–11056 Filed 5–10–90; 8:45 am]
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federal register

Friday,
May 11, 1990

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 310, 331

Hypophosphatemia and Hyperphosphatemia Drug Products for Over-the-Counter Use; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 331

[Docket No. 80N-0395]

RIN 0905-AA06

Hypophosphatemia and Hyperphosphatemia 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 any drug product labeled for over-the-counter (OTC) use in treating hypophosphatemia (abnormally low plasma level of phosphate in the blood) or hyperphosphatemia (abnormally high plasma level of phosphate in the blood) is not generally recognized as safe and effective and is misbranded. This final rule also amends the monograph for OTC antacid drug products to revise the ingredient listing for aluminum phosphate to state that this ingredient is for use only in combination with other OTC antacid ingredients, to include professional labeling for a hyperphosphatemia claim for products containing aluminum carbonate, and to include professional labeling for additional warnings for aluminum-containing antacid drug products. 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 rule, and all new data and information on hypophosphatemia and hyperphosphatemia 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 DATES: The effective date for §§ 310.541 and 310.542 is November 12, 1990, and the effective date for §§ 331.11 and 331.80 is May 13, 1991.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 9, 1980 (45 FR 81154), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking that (1) would classify OTC hypophosphatemia and hyperphosphatemia drug products as not generally recognized as safe and effective and as being misbranded and (2) would declare these products to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). The notice was based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (Miscellaneous Internal Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by March 9, 1981. Reply comments in response to comments filed in the initial comment period could be submitted by April 8, 1981.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of a small amount of trade secret information.

The agency's proposed regulation, in the form of a tentative final rule, for OTC hypophosphatemia and hyperphosphatemia drug products was published in the **Federal Register** of January 15, 1985 (50 FR 2160). Interested persons were invited to file by May 15, 1985, 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 15, 1985. New data could have been submitted until January 15, 1986, and comments on the new data until March 17, 1986. Final agency action occurs with the publication of this final rule on OTC hypophosphatemia and hyperphosphatemia drug products.

As discussed in the advance notice of proposed rulemaking for OTC hypophosphatemia and hyperphosphatemia drug products (45 FR 81154), the agency stated that conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of a final order in the **Federal Register**. However, in the proposed rule (50 FR 2160), the agency advised that the effective date of the final rule would be 12 months after the date of publication in the **Federal Register**. The agency's intent in the proposed rule was that the 12-month effective date was applicable to the "monograph" conditions in the document. In this final rule, OTC hypophosphatemia and hyperphosphatemia drug products are not generally recognized as safe and effective and are misbranded (nonmonograph conditions). In this same document, the monograph for OTC antacid drug products is being amended to include (1) a revision in the aluminum phosphate ingredient listing, (2) a professional labeling claim, and (3) professional labeling warnings (monograph conditions). Because of the nonmonograph and monograph conditions included in this document, the agency is establishing dual effective dates of 6 and 12 months, respectively. The nonmonograph conditions (§§ 310.541 and 310.542) will be effective 6 months after the date of publication of the final rule in the **Federal Register**. This 6-month effective date is consistent with other final rules promulgated by the agency establishing that certain drugs are not generally recognized as safe and effective for OTC use (see, e.g., 21 CFR 310.519 and 310.529). On or after November 12, 1990, no OTC drug products for hypophosphatemia or hyperphosphatemia may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved application under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314. Further, any OTC drug product subject to this final rule that is repackaged or relabeled after the effective date of this final rule must be in compliance with the final rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce.

The amendment to the monograph for OTC antacid drug products in this final rule (§§ 331.11 and 331.80) will be effective 12 months after the date of publication in the **Federal Register**. Therefore, on or after May 13, 1991, no OTC drug products that are subject to the monograph for OTC antacid drug products and that contain 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 they are the subject of an approved application. 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.

The agency recognizes that the Panel considered the ingredients aluminum phosphate gel and aluminum carbonate gel for use in hypophosphatemia and hyperphosphatemia, respectively. In the final monograph for OTC antacid drug products (21 CFR 331.11), these ingredients are named aluminum phosphate and aluminum carbonate. In accordance with the USAN and USP Dictionary of Drug Names (Ref. 1) and The United States Pharmacopeia XXII/ National Formulary XVII (U.S.P. XXII/ N.F. XVII) (Ref. 2), these ingredients are currently designated as aluminum phosphate gel and basic aluminum carbonate gel. Therefore, in responding to comments throughout this document, these ingredients will be referred to by their current compendial names.

In response to the proposed rule on OTC hypophosphatemia and hyperphosphatemia drug products, one drug manufacturer, one drug manufacturers' association, one professional association, and eight individuals submitted comments. No requests for oral hearing before the Commissioner were received. Copies of the comments 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.

In proceeding with this final rule, the agency has considered all comments and changes in the procedural regulations.

References

(1) "USAN and the USP Dictionary of Drug Names," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 32–33, 1989

(2) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 50–54, 1989.

I. The Agency's Conclusions on the Comments

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464), and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F. 2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

2. One comment stated that FDA cannot legally prescribe exclusive lists of terms from which indications for use for OTC drug products must be drawn and thus prohibit alternative OTC labeling terminology to described such indications which is truthful, not misleading, intelligible to the consumer. The comment noted that its views were presented to FDA in connection with the September 29, 1982 hearing on the "Exclusivity Policy."

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear a boxed are nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g). However, the above provisions are not applicable to the final rule for OTC hypophosphatemia and hyperphosphatemia drug products because there are no drug products that are generally recognized as safe and effective for OTC use for these indications.

3. Two comments objected to the characterization of the statement in the professional labeling in proposed § 331.31(a)(3) as "Warning(s)" and requested that they be changed to "Cautions." The comments contended that the proposed statements are more accurately characterized as "caution(s)" because, rather than precluding use, they provide information about potential problems. If the agency were to insist on the need for a warning in the professional labeling of OTC antacid drug products containing aluminum, one comment recommended that the "warning" be changed to a "caution" because its primary purpose is to alert the physician to a potential problem.

The "warning" statements referred to by the comments in proposed § 331.31(a)(3) are not intended for the OTC labeling of aluminum-containing antacids directed to the lay consumer, but are intended for "professional labeling" to be distributed to physicians. However, the agency considers its general policy concerning the use of the signal words "caution" or "warning" in OTC drug labeling to be equally appropriate for professional labeling of OTC drugs.

Section 502(f)(2) of the act (21 U.S.C. 352(f)(2)) states, in part, that unless exempted by regulation, the labeling for a drug must bear " * * * such adequate warnings * * * as are necessary for the protection of users." Section 330.10(a)(4)(v) of the OTC drug regulations (21 CFR 330.10(a)(4)(v)) provides that labeling of OTC drug products should include " * * * warnings against unsafe use, side effects, and adverse reactions * * *."

The agency notes that historically there has not been consistent usage of the signal words "warning" and "caution" in OTC drug labeling. For example, in §§ 369.20 and 369.21 (21 CFR 369.20 and 369.21), which list "warning" and "caution" statements for drugs, the signal words "warning" and "caution" are both used. In some instances, either of these signal words is used to convey the same or similar precautionary information.

For OTC drug labeling, FDA has concluded that the signal word "warning" is more likely to flag potential dangers so that consumers will read the information being conveyed. Therefore, FDA has determined that the signal word "warning," rather than the word "caution," will be used routinely in OTC drug labeling. In order to maintain uniformity in labeling, the agency is using this same approach for the professional labeling included in OTC drug monographs.

4. One comment considered the use of the term "magaldrate" in the labeling of

OTC antacids as "mislabeling." The comment stated that one pharmacist had incorrectly recommended a magaldrate-containing antacid as a non-aluminum-containing antacid, while a second pharmacist recognized the presence of aluminum in the antacid product. The comment questioned "why the manufacturer is allowed to use a 'made up' name to conceal the presence" of aluminum in a product.

Under section 502(e)(1) of the act (21 U.S.C. 352(e)(1)), a drug is considered misbranded if its label does not bear the established name of the drug, if one exists. The established name of a drug is defined in section 502(e)(3) of the act (21 U.S.C. 352(e)(3)), as follows: " * * * (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient * * *." The agency has further clarified this definition in 21 CFR 299.4(b) as follows: " * * * (1) an official name designated pursuant to section 508 of the act; (2) if no such official name has been designated for the drug and the drug is an article recognized in an official compendium, then the official title thereof in such compendium; and (3) if neither paragraphs (b) (1) or (2) of this section applies, then the common or usual name of the drug."

The agency recognizes the skill and experience of the United States Adopted Names Council (USAN) in deriving names for drugs. (See 21 CFR 299.4(c).) USAN chose the name "magaldrate" to represent this drug based on its guiding principles for coining adopted names for drugs (Ref. 1). These principles include, among others, suitability, simplicity, and established usage. The name "magaldrate" has appeared in an official compendium in the United States for 20 years. "Magaldrate" was included in the National Formulary XIII in 1970 (Ref. 2) and later in the United States Pharmacopeia XIX in 1975 (Ref. 3). These official compendia have been published in one volume, the United States Pharmacopeia/National Formulary (U.S.P/N.F.), since 1980, and the name "magaldrate" has been used in each edition (Refs. 4, 5, and 6).

The monograph for OTC antacid drug products has listed "magaldrate" as an active ingredient since its publication in the Federal Register of June 4, 1974 (39 FR 19862), and "magaldrate" is currently listed as a specific active ingredient in § 331.11(g)(2) of the OTC antacid monograph (21 CFR 331.11(g)(2)). The agency regrets that the individual who submitted the comment was mislead by one pharmacist and is confident that this represents an isolated incident. The vast majority of pharmacists in the United States are familiar with the chemical composition of specific ingredients in OTC drug products. Also, reference books are readily available to answer questions about a drug ingredient.

References

(1) "USAN and the USP Dictionary of Drug Names," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 640–645, 1989.
(2) "National Formulary XIII," American Pharmaceutical Association, Washington, pp. 396–397, 1970.
(3) "The United States Pharmacopeia—XIX," United States Pharmacopeial Convention, Rockville, MD, p. 290, 1975.
(4) "The United States Pharmacopeia XX—The National Formulary XV," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 456–457, 1980.
(5) "The United States Pharmacopeia XXI—The National Formulary XVI," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 607–608, 1985.
(6) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 785–786, 1989.

5. One comment requested that the professional labeling indication in proposed § 331.31(a)(4), which states "For the treatment, control, or management of hyperphosphatemia, or for use with a low phosphate diet to prevent formation of phosphate urinary stones, through the reduction of phosphates in the serum and urine," be extended to products containing aluminum hydroxide in addition to products containing aluminum carbonate (50 FR 2160 at 2166). Pointing out that reactive aluminum hydroxide gels usually contain carbonate, the comment stated that aluminum carbonate, as such, does not exist, and that conventional pharmaceutical aluminum carbonate is, in fact, a mixture of aluminum hydroxide and bicarbonate and/or carbonate species that form the hydroxy carbonate species called "basic aluminum carbonates." Noting that the British Pharmacopeia defines aluminum hydroxide gel as containing * * * varying quantities of basic aluminum carbonate and that the U.S.P. states that aluminum hydroxide gel * * * may contain varying quantities of basic aluminum carbonate and bicarbonate (Ref. 1), the comment stated that aluminum hydroxide U.S.P. and basic aluminum carbonate are essentially identical and should be recognized as such with respect to the professional labeling for phosphate binding. The submission also included an in vitro study of the relative phosphate binding capacities of commercially-available aluminum hydroxide gels and basic aluminum carbonate gels and published information on the in vivo phosphate binding ability of a range of aluminum salts (Ref. 1).

The Miscellaneous Internal Panel reviewed ingredients used in the OTC treatment of hyperphosphatemia in its report published in the Federal Register of December 9, 1980 (45 FR 81154). Only one ingredient, basic aluminum carbonate gel, was submitted for the Panel's review, and the Panel did not identify any other ingredients through its review of the literature. The Panel concluded that, although hyperphosphatemia was not amenable to OTC treatment, basic aluminum carbonate gel is safe and effective in the treatment of hyperphosphatemia under the supervision of a physician (45 FR 81154 at 81156 and 81157). Although the Panel concluded that basic aluminum carbonate gel was safe " * * * at a dose up to the equivalent of 12 g of aluminum hydroxide daily * * *," the Panel did not suggest that the professional labeling indication for hyperphosphatemia be extended to aluminum hydroxide.

The current edition of the United States Pharmacopeia/National Formulary (U.S.P. XXII/N.F. XVII), effective on January 1, 1990, defines basic aluminum carbonate gel in terms of its aluminum hydroxide equivalent content and defines aluminum hydroxide gel as containing amorphous aluminum hydroxide in which there is a partial substitution of carbonate for hydroxide (Ref. 2). The agency acknowledges that these two drugs are chemically similar. However, the comment did not submit sufficient data for the agency to determine if aluminum hydroxide is generally recognized as safe and effective for the professional labeling indication of hyperphosphatemia.

The agency believes that the most important consideration in selecting an ingredient to be used for the treatment of hyperphosphatemia is the phosphate binding capacity of the ingredient. As discussed by the Panel in its report (45 FR 81154 at 81157), some aluminum-containing compounds, when taken orally, combine with phosphate present from normal ingestion to form relatively insoluble aluminum phosphate complexes. These phosphate binding aluminum-containing compounds reduce

the amount of phosphate absorbed into the bloodstream and excreted in the urine. The in vivo and in vitro data submitted by the comment, though limited, indicate that aluminum hydroxide possesses the property of phosphate binding. In the submitted clinical study, 19 patients who were maintained by hemodialysis received 2 formulations of aluminum phosphate binders, aluminum hydroxide suspension and dried basic aluminum carbonate gel in the form of capsules (Ref. 3). In this 30-week study, patients received no treatment (i.e., no drug or placebo) for weeks 1 to 4, either aluminum hydroxide or basic aluminum carbonate gel for weeks 5 to 13, placebo for weeks 14 to 18, and either basic aluminum carbonate gel or aluminum hydroxide for weeks 19 to 27 (i.e., patients were crossed over to the phosphate binder that was not given during weeks 5 to 13), and no treatment for weeks 28 to 30. Of the 19 patients, 5 did not complete the last phase of the study (weeks 28 to 30), and 1 patient failed to complete half of the study. The results showed that aluminum hydroxide was statistically the same as basic aluminum carbonate gel in lowering plasma phosphate at one dose, equivalent to 170 milligrams of aluminum. However, the in vitro data, although also limited, show that basic aluminum carbonate gel has consistently higher phosphate binding capacity than aluminum hydroxide when compared per milligram of aluminum hydroxide. The agency does not consider these data as sufficient to establish general recognition of effectiveness to support a professional labeling indication for aluminum hydroxide for this use. If, in the future, additional data are submitted in support of the use aluminum hydroxide for the professional labeling indication for the treatment of hyperphosphatemia, the agency will consider this issue further. Interested parties should meet with the agency to ascertain what additional data are needed.

References

(1) Comment No. C00016, Docket No. 80N–0395, Dockets Management Branch.

(2) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 50–52, 1989.

(3) Johnson, W.J., and P.C. O'Brien, "Effectiveness of Intestinal Phosphate Binders in Patients Maintained by Hemodialysis," *Nephron*, 21:123–130, 1978.

6. Two comments objected to the warnings proposed for the professional labeling of OTC aluminum-containing antacid drug products and requested that neither warning be included in the antacid monograph. The warnings proposed for inclusion in § 331.31(a)(3) of the antacid monograph were as follows:

(i) Evidence suggests that elevated tissue aluminum levels have a role in development of the dialysis encephalopathy syndrome. A number of cases have been associated with elevated aluminum levels in the dialysate water. There is also evidence that small amounts of ingested aluminum are absorbed from the gastrointestinal tract, and it is likely that renal excretion of absorbed aluminum is impaired in renal failure. Prolonged use of aluminum-containing antacids in such patients may contribute to increased tissue levels of aluminum.

(ii) Aluminum forms insoluble complexes with phosphate in the gastrointestinal tract, thus decreasing phosphate absorption. Prolonged use of aluminum-containing antacids by normophosphatemic patients may result in hypophosphatemia if phosphate intake is not adequate. In its more severe forms, hypophosphatemia can lead to anorexia, malaise, muscle weakness, and osteomalacia.

Referring to the warning in paragraph (i) above, the comments stated that the warning relates to individuals with impaired renal function and those receiving kidney dialysis treatment who are maintained under the close supervision of a specialist in renal disease. Because of this supervision, one comment argued that it would be "highly improbable" that such patients would be exposed to medications which might exacerbate their condition. The comment added that inclusion of an 80-word warning in the professional labeling of aluminum-containing antacid drug products is irrelevant, unnecessary, and excessive. The other comment stated that this warning has no bearing on the promotion of the product to the health-care professional for general antacid uses.

Regarding the proposed warning in paragraph (ii) above, the comments stated that this warning is relevant only in situations where dietary phosphate is not adequate in normophosphatemic patients. The comment stated that dietary phosphate deficiency in man essentially does not occur given that "phosphate is available in all foods consisting of plant and animal cells as well as all dairy products." One of the comments noted that the possibility of the occurrence of disturbances in mineral metabolism in patients with normal renal function is highly unlikely even where there is abuse of the aluminum-containing antacids by very prolonged use of high doses. The comment mentioned that a literature search covering 1966 to 1984 produced only 16 such cases (Ref. 1). The comments concluded that the warning is unnecessary and should not be required in the professional labeling of OTC aluminum-containing antacid drug products.

One of the comments also recommended that if the agency concludes that warnings are necessary for the professional labeling of OTC aluminum-containing antacid drug products, the wording should be revised as follows:

For products indicated only for antacid use. Prolonged use of aluminum-containing antacids in patients *with renal disease* may contribute to increased tissue levels of aluminum.

For products indicated for use in hyperphosphatemia. Evidence suggests that elevated tissue aluminum levels have a role in the development of the dialysis encephalopathy syndrome. A number of cases have been associated with elevated aluminum levels in the dialysate water. There is *some* evidence that small amounts of ingested aluminum *may* be absorbed from the gastrointestinal tract and it is *possible* that renal excretion of absorbed aluminum is impaired in renal disease.

In the notice of proposed rulemaking on hypophosphatemia and hyperphosphatemia drug products, published in the **Federal Register** of January 15, 1985 (50 FR 2160), the agency reviewed all the available data on the involvement of aluminum as an etiological factor in various conditions and concluded that it would be appropriate to provide additional information in the professionsl labeling section of the antacid monograph for aluminum-containing antacid drug products. Accordingly, the agency proposed that the two warnings in paragraphs (i) and (ii) above be added to § 331.31(a) of the antacid monograph.

The comments submitted no new data establishing that these warnings are not needed. The agency does not agree with the comments that the warnings proposed for the professional labeling of aluminum-containing antacid drug products are unnecessary and irrelevant. The agency acknowledges that specialists may have knowledge of information concerning the safe and effective use of a product. However, the agency does not agree that such knowledge makes the inclusion of this information in the labeling unnecessary. The agency believes that these warnings in the professional labeling of OTC drug products provide physicians, including physicians who are not specialists in the treatment of renal disease, with the kind of information that is presented in the package inserts of prescription drug products. In addition, the agency

believes that the comments recognize the validity of the concerns raised by this warning information, which is intended to be informative to physicians who are treating patients with any of the aluminum-containing antacid drug products. The agency finds that the alternative warnings submitted by one comment are inadequate because they do not include any reference to the effect of aluminum on normophosphatemic patients and because the suggested revisions weaken the intent of the statement in (i) by changing key words, e.g., "may be absorbed" instead of "are absorbed." For the above reasons, the agency disagrees with the comments and is amending proposed § 331.31(a) to add the information proposed in § 331.31(a)(3)(ii). In addition, another comment submitted a number of references from the scientific literature that have led the agency to expand and revise the information contained in proposed § 331.31(a)(3)(i). (See discussion of the revised warning in comment 7 below.)

Reference

(1) Comment No. C00018, Docket No. 80N–0395, Dockets Management Branch.

7. One comment contended that the professional labeling warnings proposed in § 331.31(a)(3) for aluminum-containing antacids are inadequate because they do not discuss the direct toxicity of aluminum to bone tissue. Stating that the proposed professional warnings fail to discuss the large body of evidence which indicates that orally administered aluminum can accumulate in bone tissue and be harmful to the growth of bone, the comment included references from the scientific literature in support of this position (Ref. 1) and requested that the warnings be expanded to describe the toxic effects of aluminum to bone tissue.

The agency has reviewed all the available data on the relationship between aluminum-containing antacids and bone toxicity and concurs with the comment that the body of evidence presented supports expansion of the professional labeling warnings for aluminum-containing antacids in § 331.31(a)(3) of the antacid monograph. When the agency last evaluated this issue prior to publishing the proposed antacid monograph amendment to add professional labeling warnings for OTC aluminum-containing antacids (50 FR 2160 at 2165), the relationship of aluminum to bone disease was not established. There was even some doubt about the relationship of aluminum to encephalopathy (a toxic degeneration of the brain) at that time. Subsequently it has become clear that both encephalopathy and osteomalacia (softening of the bones) can be caused by long-term use of aluminum in renal dialysis patients. Therefore, in this amendment to the antacid monograph, the agency has reconsidered the proposed warnings and included information about the direct toxic effects of aluminum on bone mineralization in these patients.

Long-term use of aluminum-containing antacids contributes to dialysis osteomalacia (Refs. 2 through 10). Although only a small fraction of ingested aluminum is absorbed, that amount must be removed by functioning kidneys, bile secretion, or dialysis, or else it will accumulate. Dialysis does not remove aluminum well because the aluminum is bound to albumin and transferrin, which do not cross dialysis membranes (Ref. 11). When aluminum accumulates, it tends to be deposited in bone (Refs. 12 through 15) at the mineralization front, blocking mineralization of newly formed bone, increasing calcium loss from bone into serum, and producing osteomalacia (Refs. 16 through 20). The agency recognizes that renal osteodystrophy (defective bone formation) is very complicated and results not only from aluminum excess but also from hyperparathyroidism, acidosis, and abnormal metabolism of vitamin D, calcium, and phosphorus. These factors have little to do with aluminum excess (Refs. 21 and 22), and removal of aluminum will not correct any of these other factors. Nevertheless, the agency believes that the role of aluminum is significant and that attempts should be made to reduce its contribution to renal osteodystrophy.

In addition, the agency points out that the dialysis encephalopathy that was due to aluminum (as discussed above) resulted from two factors: (1) Oral aluminum-containing antacids taken as phosphate binders and (2) aluminum-containing dialysis fluids. Removal of aluminum from dialysis fluids has reduced the encephalopathy that was seen in association with dialysis.

For the above reasons, the agency is expanding and revising the warning in proposed § 331.31(a)(3)(i) to read as follows:

Prolonged use of aluminum-containing antacids in patients with renal failure may result in or worsen dialysis osteomalacia. Elevated tissue aluminum levels contribute to the development of the dialysis encephalopathy and osteomalacia syndromes. Small amounts of aluminum are absorbed from the gastrointestinal tract and renal excretion of aluminum is impaired in renal failure. Aluminum is not well removed by dialysis because it is bound to albumin and transferrin, which do not cross dialysis membranes. As a result, aluminum is deposited in bone, and dialysis osteomalacia may develop when large amounts of aluminum are ingested orally by patients with impaired renal function.

References

(1) Comment No. C00017, Docket No. 80N–0395, Dockets Management Branch.

(2) "Toxicologic Consequences of Oral Aluminum," *Nutrition Reviews*, 45:72–74, 1987.

(3) Milliner, D.S., et al., "Plasma Aluminum Levels in Pediatric Dialysis Patients: Comparison of Hemodialysis and Continuous Peritoneal Dialysis," *Mayo Clinic Proceedings*, 62:269–274, 1987.

(4) Hodsman, A.B., et al., "Do Serum Aluminum Levels Reflect Underlying Skeletal Aluminum Accumulation and Bone Histology Before or After Chelation by Deferoxamine?" *Journal of Laboratory and Clinical Medicine*, 16:674–681, 1985.

(5) Winney, R.J., J.F. Cowie, and J.S. Robson, "What is the Value of Plasma/Serum Aluminum in Patients With Chronic Renal Failure?" *Clinical Nephrology*, 24:S2–S8, 1985.

(6) Andreoli, S.P., J.A. Smith, and J.M. Bergstein, "Aluminum Bone Disease in Children: Radiographic Features from Diagnosis to Resolution," *Radiology*, 156:663–667, 1985.

(7) Recker, R.R., et al., "Evidence for Aluminum Absorption from the Gastrointestinal Tract and Bone Deposition by Aluminum Carbonate Ingestion with Normal Renal Function," *Journal of Laboratory and Clinical Medicine*, 90:810–815, 1977.

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(9) McCarthy, J.T., et al., "Interpretation of Serum Aluminum Values in Dialysis Patients," *American Journal of Clinical Pathology*, 86:629–636, 1986.

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(11) Alfrey, A.C., "Aluminum Metabolism," *Kidney International*, 29 (Supplement 18): S–8–S–11, 1986.

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(14) Andress, D.L., et al., "Early Deposition of Aluminum in Bone in Diabetic Patients on Hemodialysis," *New England Journal of Medicine*, 316:292–296, 1987.

(15) Chazan, J.A., "Aluminum in Bone in Diabetic Patients," *New England Journal of Medicine*, 317:386–387, 1987.

(16) O'Connor, M., et al., "Aluminum-Related Bone Disease: Correlation Between Symptoms, Osteoid Volume, and Aluminum Staining," *American Journal of Clinical Pathology*, 86:168–174, 1986.
(17) Andress, D.L., et al., "Osteomalacia and Aplastic Bone Disease in Aluminum-Related Osteodystrophy," *Journal of Clinical Endocrinology and Metabolism*, 65:11–16, 1987.
(18) Cournot-Witmer, G., et al., "Effect of Aluminum on Bone and Cell Localization," *Kidney International*, 29 (Supplement 18): S–37–S–40, 1986.
(19) Posner, A.S., N.C. Blumenthal, and A.L. Boskey, "Model of Aluminum-Induced Osteomalacia: Inhibition of Apatite Formation and Growth," *Kidney International*, 29 (Supplement 18): S–17–S–19, 1986.
(20) Dustan, C.R., et al., "Clinical Investigations: Effect of Aluminum and Parathyroid Hormone on Osteoblasts and Bone Mineralization in Chronic Renal Failure," *Calcified Tissue International*, 36:133–138, 1984.
(21) Slatopolsky, E., "The Interaction of Parathyroid Hormone and Aluminum in Renal Osteodystrophy," *Kidney International*, 31:842–854, 1987.
(22) Piraino, B.M., et al., "Spontaneous Hypercalcemia in Patients Undergoing Dialysis: Etiologic and Therapeutic Considerations," *American Journal of Medicine*, 80:607–615, 1986.

8. One comment requested that the agency accept the recommendation of the Miscellaneous Internal Panel that a warning be added to the labeling of OTC aluminum-containing antacid drug products to discourage their use, without the supervision of a physician, by patients with kidney disease (45 FR 81154 at 81157). The comment maintained that current medical literature indicates: (1) That children with renal failure are the most susceptible victims of aluminum intoxication from the use of OTC antacids and (2) that some adult patients suffering from aluminum intoxication have also benefited from restriction of aluminum-containing antacids. The comment cited clinical reports to support this position (Ref. 1). In addition, the comment stated that the agency's decision in the tentative final monograph (50 FR 2160 at 2163) against requiring such a warning is inconsistent with the comparable warning currently required in 21 CFR 331.30(c)(4) for magnesium-containing antacids, which states for products containing more than 50 milliequivalents (mEq) of magnesium in the recommended daily dosage: "Do not use this product except under the advice and supervision of a physician if you have kidney disease." The comment argued that the lack of a warning on OTC aluminum-containing antacids against their use by patients with kidney disease denies potential users of important information in their own health care or in the care they provide to a young child with kidney disease. The comment contended that the proposed professional labeling warnings will not be sufficient to get adequate information into the hands of individual users of OTC aluminum-containing antacids because these products are usually sold without a physician's supervision. Therefore, the comment requested that the agency add an appropriate statement to the labeling of OTC aluminum-containing antacids warning against use of these products by patients with kidney disease, without the supervision of a physician.

The Advisory Review Panel on OTC Antacid Drug Products in its report (38 FR 8714 at 8719) recommended that a warning was needed on OTC products to advise patients with kidney disease not to use magnesium-containing antacids that contain more than 50 mEq of magnesium in the recommended daily dose even when such use would not exceed the recommended 2-week limitation period. That Panel did not recommend a similar warning for OTC aluminum-containing antacids. The agency has considered the submitted information and all other available information and concludes that there is no evidence that short term (less than 2 weeks), intermittent use of antacids for OTC indications of heartburn, sour stomach, and/or acid indigestion produces aluminum intoxication in either adults or children. Therefore, on the basis of present safety evidence concerning aluminum-containing antacids, the 2-week limitation on use without a doctor's supervision, the intermittent nature of use (which is primarily by adults), and the warnings in the professional labeling section of the monograph which provide adequate information for health professionals to alert patients who will use these products for long periods of time, the agency concludes that a separate OTC warning is not indicated at this time.

Reference

(1) Comment No. C00017, Docket No. 80N–0395, Dockets Management Branch.

II. Summary of Significant Changes From the Proposed Rule

FDA has considered the comments and other relevant information and concludes that it will adopt the proposed rule (January 15, 1985; 50 FR 2160) with the changes described in FDA's responses to the comments above and with other changes described in the summary below.

1. The ingredient names aluminum carbonate and aluminum phosphate in 21 CFR 331.11(a) (1) and (4), respectively, are being changed to basic aluminum carbonate gel and aluminum phosphate gel, respectively, to be in accord with current names in the USAN and the USP Dictionary of Drug Names and the U.S.P. XXII/N.F. XVII.

2. The professional labeling warning concerning the effects of aluminum-containing antacids on patients with renal failure has been revised and expanded to address the direct toxic effects of aluminum on bone mineralization in these patients. (See comment 7 above.)

3. In the **Federal Register** of November 16, 1988 (53 FR 46190 at 46191), the agency proposed to redesignate the professional labeling section of the antacid monograph from § 331.31 to § 331.80 in accordance with the format of other recently published tentative final and final monographs. In this final rule, the redesignation of § 331.31 to § 331.80 is made final. Additionally, to conform with the format of other recently published tentative final and final monographs, the agency has reversed the order of the indication and warning statements in the professional labeling section. Therefore, the indications statement now appears as § 331.80(a)(3) and the warning statements now appear as § 331.80(a)(4) (i) and (ii).

III. The Agency's Final Conclusions on OTC Hypophosphatemia and Hyperphosphatemia Drug Products

The agency has determined that no OTC drug product has been found to be generally recognized as safe and effective and not misbranded for use in the treatment of hypophosphatemia or hyperphosphatemia. Therefore, all such drug products, including those containing the ingredients aluminum phosphate gel and basic aluminum carbonate gel, which were reviewed by the Panel, are considered nonmonograph and misbranded under section 502 of the act (21 U.S.C. 352) and are new drugs under section 201(p) of the act (21 U.S.C. 321(p)) for which an approved application under section 505 of the act (21 U.S.C. 355) and part 314 of the regulations (21 CFR part 314) is required for marketing. As an alternative, where there are adequate data establishing general recognition of safety and effectiveness, such data may be submitted in a citizen petition to establish a monograph for OTC drug products for the treatment of hypophosphatemia or hyperphosphatemia. (See 21 CFR 10.30.)

Any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce after the effective date of this final rule that is not in compliance with the regulation is subject to regulatory action.

Although the agency has determined that OTC use of drug products for hypophosphatemia and hyperphosphatemia is not appropriate because such conditions are not amenable to self-diagnosis or self-treatment and treatment of these conditions should be restricted to the supervision of a physician, the agency acknowledges that cetain OTC antacid drug products are used to treat these conditions. Accordingly, the agency is amending the monograph for OTC antacid drug products to include professional labeling for the use of basic aluminum carbonate gel-containing antacid drug products in the treatment of hyperphosphatemia and professional labeling warnings addressing the effects of long-term use of aluminum-containing antacids for professional indications. This final rule also amends the ingredient listing for aluminum phosphate gel to state that this ingredient is for use only in combination with other OTC antacid ingredients.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (50 FR 2160 at 2166). 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 hypophosphatemia and hyperphosphatemia drug products, 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 hypophosphatemia and hyperphosphatemia drug products is not expected to pose such an impact on small businesses. 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 in 21 CFR

Part 310: Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Part 331: Antacid drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, subchapter D of chapter I of title 21 of the Code of Federal Regulations 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. Sections 310.541 and 310.542 are added to subpart E to read as follows:

§ 310.541 Over-the-counter (OTC) drug products containing active ingredients offered for use in the treatment of hypophosphatemia.

(a) Hypophosphatemia is a condition in which an abnormally low plasma level of phosphate occurs in the blood. This condition is not amenable to self-diagnosis or self-treatment. Treatment of this condition should be restricted to the supervision of a physician. For this reason, any drug product containing ingredients offered for OTC use in the treatment of hypophosphatemia cannot be considered generally recognized as safe and effective.

(b) Any drug product that is labeled, represented, or promoted for OTC use in the treatment of hypophosphatemia is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act), for which an approved application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for OTC use in the treatment of hypophosphatemia is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in Part 312 of his chapter.

(d) After November 12, 1990, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

§ 310.542 Over-the-counter (OTC) drug products containing active ingredients offered for use in the treatment of hyperphosphatemia.

(a) Hyperphosphatemia is a condition in which an abnormally high plasma level of phosphate occurs in the blood. This condition in not amenable to self-diagnosis or self-treatment. Treatment of this condition should be restricted to the supervision of a physician. For this reason, any drug product containing ingredients offered for OTC use in the treatment of hyperphosphatemia cannot be considered generally recognized as safe and effective.

(b) Any drug product that is labeled, represented, or promoted for OTC use in the treatment of hyperphosphatemia is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act), for which an approved application under section 505 of the act and part 314 of this chapter is required for marketing. In the absence of an approved application, such product is also misbranded under section 502 of the act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for use in the treatment of hyperphosphatemia is safe and effective for the purpose intended must comply with the requirements and procedures governing use of investigational new drugs set forth in part 312 of this chapter.

(d) After November 12, 1990, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

3. The authority citation for 21 CFR part 331 continues to read as follows:

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).

4. Section 331.11 is amended by revising paragraphs (a) (1) and (4) to read as follows:

§ 331.11 Listing of specific active ingredients.

(a) * * *

(1) Basic aluminum carbonate gel.

* * * * *

(4) Aluminum phosphate gel when used as part of an antacid combination product and contributing at least 25 percent of the total acid neutralizing capacity; maximum daily dosage limit is 8 grams.

* * * * *

5. Section 331.31 is redesignated as § 331.80 and new paragraphs (a) (3) and (4) are added to read as follows:

§ 331.80 Professional labeling.

(a) * * *

(3) *For products containing basic aluminum carbonate gel identified in § 331.11(a)(1)—Indication.* "For the treatment, control, or management of hyperphosphatemia, or for use with a low phosphate diet to prevent formation of phosphate urinary stones, through the reduction of phosphates in the serum and urine."

(4) *For products containing aluminum identified in § 331.11(a)—Warnings.* (i) Prolonged use of aluminum-containing antacids in patients with renal failure may result in or worsen dialysis osteomalacia. Elevated tissue aluminum levels contribute to the development of the dialysis encephalopathy and osteomalacia syndromes. Small amounts of aluminum are absorbed from the gastrointestinal tract and renal excretion of aluminum is impaired in renal failure. Aluminum is not well removed by dialysis because it is bound to albumin and transferrin, which do not cross dialysis membranes. As a result, aluminum is deposited in bone, and dialysis osteomalacia may develop when large amounts of aluminum are ingested orally by patients with impaired renal function.

(ii) Aluminum forms insoluble complexes with phosphate in the gastrointestinal tract, thus decreasing phosphate absorption. Prolonged use of aluminum-containing antacids by normophosphatemic patients may result in hypophosphatemia if phosphate intake is not adequate. In its more severe forms, hypophosphatemia can lead to anorexia , malaise, muscle weakness, and osteomalacia.

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Dated: March 27, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

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