brucellosis free herds moving interstate are not affected by this change.

The groups affected by this action will be herd owners in Nevada, as well as buyers and importers of Nevada cattle.

This action could affect an estimated 1,700 cattle herds in Nevada, 98 percent of which are owned by small entities. Most of these herds are not certified-free. Test-eligible cattle offered for sale from other than certified-free herds must have a negative test under present Class A status regulations. Last year Nevada tested 16,249 cattle under those regulations. This testing cost approximately $7 per head, or $113,743. If such testing is distributed equally among all herds potentially affected by this regulation, Class Free status could save herd owners approximately $67 per year for each herd.

Therefore, we have determined that changing Nevada's brucellosis status will not significantly affect market patterns, and will not have a significant economic impact on the small entities affected by this rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

List of Subjects in 9 CFR Part 78

Animal diseases, Brucellosis, Cattle, Hogs, Quarantine, Transportation.

PART 78—BRUCELLOSIS

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 78 and that was published at 55 FR 37312–37313 on September 11, 1990.

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done in Washington, DC, this 7th day of January 1991.

Robert Melland,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91–673 Filed 1–10–91; 8:45 am]

BILLING CODE 3410-34-M

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9 CFR Part 78

[Docket No. 90–240]

Brucellosis in Cattle; State and Area Classifications

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule.

SUMMARY: We are affirming without change an interim rule that amended the brucellosis regulations concerning the interstate movement of cattle by changing the classification of Idaho from Class A to Class Free. We have determined that Idaho meets the standards for Class Free status. This action relieves certain restrictions on the interstate movement of cattle from Idaho.

EFFECTIVE DATE: February 11, 1991.

FOR FURTHER INFORMATION CONTACT: Dr. John D. Kopec, Senior Staff Veterinarian, Cattle Diseases and Surveillance Staff, VS, APHIS, USDA, room 729, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782 (301) 436–6188.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule effective October 9, 1990, and published in the **Federal Register** on October 12, 1990 (55 FR 41505–41507, Docket Number 90–178), we amended the regulations in 9 CFR part 78 that provide a system for classifying States or portions of States according to the rate of brucella infection present, and the general effectiveness of a brucellosis control and eradication program. We removed Idaho from the list of Class A States in § 78.41(b) and added it to the list of Class Free States in § 78.41(a).

Comments on the interim rule were required to be received on or before December 11, 1990. We did not receive any comments. The facts presented in the interim rule still provide a basis for the rule.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office Management and Budget has waived its review process required by Executive Order 12291.

Cattle moved interstate are moved for slaughter, for use as breeding stock, or for feeding. Changing the status of Idaho from Class A to Class Free reduces certain testing and other requirements governing the interstate movement of cattle from Idaho. Testing requirements for cattle moved interstate for immediate slaughter or to quarantined feedlots are not affected by this change. Cattle from certified brucellosis-free herds moving interstate are not affected by this change.

The groups affected by this action will be herd owners in Idaho, as well as buyers and importers of Idaho cattle.

There are an estimated 16,000 herds in Idaho, 98 percent of which are owned by small entities that would be affected by this rule. Most of these herds are not certified-free. Test-eligible cattle offered for sale from other than certified-free herds must have a negative test under present Class A status regulations, but not under regulations concerning Class Free status. Last year Idaho tested 86,454 cattle under the Class A status regulations. This testing costs approximately $3.50 per head, or $302,589. If such testing were distributed equally among all herds affected by this rule, Class Free status would save less than $19 per herd.

Therefore, we have determined that changing Idaho's brucellosis status to Class Free should not significantly affect market patterns, and will not have a significant economic impact on the small entities affected by this rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

List of Subjects in 9 CFR Part 78

Animal diseases, Brucellosis, Cattle, Hogs, Quarantine, Transportation.

Accordingly, we are adopting as a final rule, without change, the interim rule amending 9 CFR 78.41 (a) and (b) that was published at 55 FR 41505–41507 on October 12, 1990.

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done in Washington, DC, this 7 day of January 1991.

Robert Melland,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91–675 Filed 1–10–91; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 90F-0021]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2,2′-methylenebis(4-methyl-6-*tert*-butylphenol) monoacrylate as an antioxidant in styrene block polymers intended for use in contact with food. This action is in response to a petition filed by Sumitomo Chemical America, Inc.

DATES: Effective January 11, 1991; written objections and requests for a hearing by February 11, 1991.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 8, 1990 (55 FR 4481), FDA announced that a food additive petition (FAP OB4190) had been filed by Sumitomo Chemical America, Inc., 345 Park Ave., New York, NY 10154, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of 2-*tert*-butyl-6-(3-*tert*-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenylacrylate as an antioxidant in styrene block polymers intended for use on contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use as an antioxidant in styrene block polymers intended to contact food is safe, and that the regulations in 21 CFR 178.2010(b) should be amended as set forth below.

The agency also notes that the subject additive, 2-*tert*-butyl-6-(3-*tert*-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenylacrylate (CAS Reg. No. 61167–58–6) is currently listed in § 178.2010 under the synonym 2,2′-methylenebis(4-methyl-6-*tert*-butylphenol) monoacrylate. Accordingly, this amendment will add the proposed use of the additive to the currently listed use of the additive in 21 CFR 178.2010.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before February 11, 1991, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.2010 is amended in the table in paragraph (b) by revising the "Limitations" column for the entry "2,2′-methylenebis(4-methyl-6-*tert*-butylphenol) monoacrylate * * *" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
2,2′-Methylenebis(4-methyl-6-*tert*-butylphenol) monoacrylate (CAS Reg. No. 61167-58-6).	For use only: 1. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter. 2. At levels not to exceed 0.5 percent by weight of styrene block ploymers complying with § 177.1810 of this chapter.
* * * * *	

Dated: December 31, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-631 Filed 1-10-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 89F-0409]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in propylene polymers intended for use in contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K. K.

DATES: Effective January 11, 1991; written objections and requests for a hearing by February 11, 1991.

ADDRESSES: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 24, 1989 (54 FR 43338), FDA announced that a food additive petition (FAP 9B4165) had been filed by Adeka Argus Chemical Co., Ltd. (now known as Asahi Denka Kogyo K. K.), 5-2-13 Shirahata, Urawa, Saitama, Japan, proposing that § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) be amended to provide for the safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in propylene polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe and is therefore amending 21 CFR 178.3295 as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before February 11, 1991, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.3295 is amended in the table by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
* * * * *	
Sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl) phosphate (CAS Reg. No. 85209-91-2).	For use only as a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from propylene). The finished polymers contact food only of the types I, II, IV-B, VI-B, VII-B, and VIII as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use B through G described in Table 2 of § 176.170(c) of this chapter; or food of all types, limited to conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.

Dated: December 31, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-634 Filed 1-10-91; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 76

[Order No. 1462-90]

Regulations Implementing Civil Penalties Under the Anti-Drug Abuse Act of 1988

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Final rule.

SUMMARY: These regulations implement section 6486 of the Anti-Drug Abuse Act of 1988, Public Law 100–690 (hereinafter the Act), 21 U.S.C. 844a, which authorizes civil penalties of up to $10,000 for the possession of small amounts of certain controlled substances. The rules set forth the procedures to be followed in all administrative proceedings brought by the United States seeking the assessment of such a civil penalty for possession of "personal use amounts" by respondents who have violated this Act.

EFFECTIVE DATE: February 11, 1991.

FOR FURTHER INFORMATION CONTACT: Charles W. Sorenson, Jr., Room 3531, Department of Justice, 10th and Constitution Avenue NW, Washington, DC 20530. Tel. No. (202) 514–4020. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

Section 6486 of the Anti-Drug Abuse Act of 1988 (Pub. L. 100–690), 21 U.S.C. 844a, establishes a civil penalty not to exceed $10,000 for knowingly possessing certain designated controlled substances in "personal use amounts," as defined in regulations promulgated by the Attorney General. The Act authorizes the Attorney General to assess such a civil penalty in an administrative proceeding that includes the opportunity for a hearing on the record. In the event the Attorney General issues such an order assessing a civil penalty against an individual, the Act authorizes the individual to bring an action in Federal District Court. In such an action the law and facts relating to the violation and assessment shall be determined *de novo*. The Act also provides for expungement of the record of administrative proceedings for assessment of a civil penalty if certain conditions are met.

Proposed regulations implementing section 6486 were developed by the Department of Justice and were published in the **Federal Register** on December 13, 1989 (54 FR 51206), for public comment. The proposed regulations, *inter alia,* define the term "personal use amounts," and set forth detailed procedures to be used in the administrative proceedings for assessment of a civil penalty. With certain exceptions, the administrative procedures proposed generally follow the procedures set out in 28 CFR part 68 and 5 U.S.C. 554. The proposed regulations provide for: Notice to a respondent of the intent to assess a civil penalty; complaint, answer, prehearing, and discovery procedures; the opportunity for a hearing before an Administrative Law Judge (hereinafter Judge); and procedural and evidentiary standards governing the hearing. Under the proposed regulations, after a hearing and the entry of an order by the Judge, the order would be subject to review by the Attorney General. The Attorney General has the power to accept that order, modify it, or set it aside. The Attorney General's order, or the Judge's order in the case in which the Attorney General does not enter a new order, is the final agency action subject to review by a United States District Court. In accordance with the Act, the Attorney General also has the power later to expunge the record relating to a civil penalty if certain provisions are met.

In response to the publication of the proposed rules, comments were received from various individuals and organizations. Many of the comments received were directed at the perceived problems with the statute itself or the standards required by the statute—matters which are beyond the scope of these regulations. Several comments raised concerns about perceived constitutional problems with the administrative proceedings. Other comments were directed at practical difficulties in implementing the statute and regulations. Each of the comments were read and analyzed by the Department during the process by which the final regulations were drafted. After thorough consideration of the viewpoints expressed in the comments, changes in the proposed regulations were made which are responsive to many of the comments, incorporating specific suggestions where appropriate. In addition, as a result of further reflection upon the proposed regulations, other changes were made where necessary to clarify and improve the procedures established by the regulations. A brief discussion of the comments and the Department's responses follows:

II. Discussion of Comments

One comment questioned the definition of "personal use amount" in paragraph 76.2(h) of the proposed regulations, suggesting that the quantities set for the listed controlled substances were too low and that the listing of specific factors was unnecessary and confusing, and could result in rigid application of the regulations by ALJ's and courts. We believe that this comment substantially misperceives the intent of this provision and the role of the factors in determining if a "personal use amount" is involved. As clearly reflected in paragraph 76.2(h), the determinative threshold issue for applicability of the civil penalty statute and regulations in each case is whether the possession of a particular controlled substance occurred in circumstances "where there is no other evidence of an intent to distribute, or to facilitate the manufacturing, compounding, processing, delivering, importing or exporting of any controlled substance." The first five factors listed in the definition are those which, based on experience, are considered to be directly relevant to this question and are intended to provide guidance in making the ultimate determination. As the regulations indicate, however, these factors are not to be considered conclusive, and the factors are not intended to be exclusively or rigidly applied. Thus, in an appropriate circumstance other evidence regarding an intent to distribute could be considered.

Similarly, the sixth factor setting forth quantities of particular controlled substances is intended to provide guidance as to what amounts clearly would appear to be consistent with possession of the controlled substance for personal use, but it is not intended to preclude a finding, based upon appropriate evidence, that possession of quantities in excess of those listed constitutes possession for "personal use" within the meaning of the statute and regulations. To clarify this point, language has been added to § 76.2(h) to the effect that "amounts in excess of those listed in § 76.2(h)(6) may be determined to be personal use amounts where circumstances indicate possession of the substance without an intent to distribute or to facilitate the manufacturing, compounding processing, delivering, importing or exporting of the controlled substance."

Another comment, made by two organizations submitting comments, was directed at the process by which an individual is notified that a civil penalty is being sought from that individual. An enforcement proceeding under the regulations is commenced by the issuance by the appropriate United States Attorney's Office of a "Notice of Intent to Assess Civil Penalty," which under the proposed § 76.6 could be delivered or mailed to the respondent. The commenters urged that the proposed mail notice mechanism was inadequate, particularly in light of the fact that under § 76.4(c) of the regulations, if a respondent fails to serve an answer to the notice and request a hearing, a non-appealable final order assessing a penalty may entered. It was suggested that assessing a penalty after notice by letter sent to an incorrect or old address would violate due process.

We agree that the initial notice procedure contained in the proposed rules could be improved, and have revised § 76.6(b) of the regulations to require that the Notice of Intent to Assess Civil Penalty must be served by personal delivery or by registered or certified mail, return receipt requested. The intent of this provision is to ensure that a respondent against whom proceedings are initiated has actual notice of those proceedings, and that an order assessing a penalty is not entered in situations in which there is no evidence that the respondent actually received notice. Similar revisions have been made with regard to service of the complaint and service of the notice of a hearing.

The regulation also has been revised to clarify that the 30-day period within which the respondent must reply to the notice does not begin until the respondent is served with the notice. In addition, upon further review of the proposed § 76.4 notice procedures in light of the potential consequences of a civil penalty proceeding, modification of the requirements for the content of the notice has been made to ensure that a respondent is adequately informed of the nature of the proceedings, the respondent's obligations and liabilities, and the respondent's available rights.

Several comments suggested that various provisions of the proposed regulations are inconsistent with a respondent's constitutional rights, particularly the Fifth and Sixth Amendment rights relating to criminal proceedings. Although specific constitutional issues raised in the comments will be addressed below in the context of the particular proposed rules provisions implicated, it must be noted generally that the rules have never been intended to define or enumerate exhaustively the various constitutional or statutory rights that may be applicable to or available in the civil penalty administrative proceedings. Instead, it has been expected that application of the rules would require resort to generally controlling law, and that the rules would be interpreted and applied in a manner that is consistent with established constitutional principles. Nevertheless, an attempt has been made in the final rules to make this point clear, particularly where specific provisions of the proposed regulations might be interpreted in a manner that may be inconsistent with established constitutional or statutory rights.

Several comments were directed at aspects of the proposed rules that were seen as violating the Fifth Amendment privilege against self-incrimination, particularly those provisions relating to the required Answer to a Notice of Intent to Assess a Civil Penalty and the required Answer to a Complaint (see proposed §§ 76.4(c), 76.9). The regulations have been modified to clarify that all aspects of the proposed administrative process are subject to any applicable privileges, including the respondent's Fifth Amendment privilege against self-incrimination. Thus, the Notice of Intent to Assess Civil Penalty (§ 76.4(b)) must inform a respondent that any statement given may be used against the respondent in this or any other proceeding, and that in responding to the Notice, the respondent may be able to assert the privilege against self-incrimination as to appropriate, specific allegations. Similarly, § 76.9(c) relating to the Answer to the Complaint has been revised to provide that the privilege may be asserted in appropriate circumstances and will have the effect of a denial. In addition, the discovery provision (§§ 76.21, 76.24) have been clarified to reflect the potential applicability of the privilege against self-incrimination in that context.

Commenters also suggested that because of double jeopardy problems inherent in subsequent criminal prosecutions for the same conduct, the proposed civil penalties regulations should be amended to provide that the civil penalty process is the exclusive sanction for the conduct and cannot be followed by a criminal prosecution. We do not agree that such a modification is appropriate under the statute or the law of the double jeopardy. First, as evidenced by the statute and its legislative history, the Act establishes a civil, rather than criminal, penalty mechanism, which does not, on its face, implicate the double jeopardy clause. Also, as the comments on the regulations recognized, the statute and regulations prohibit the use of the civil penalty process where there has been a prior controlled substance conviction. Thus, it is unlikely that a civil penalty action would be brought in circumstances where the bringing of that action would constitute double jeopardy.

The proper forum and time to address any conceivable double jeopardy implications of subsequent criminal prosecutions arising out of the same conduct as that involved in the civil penalty proceeding would be in the content of any such criminal actions themselves. It would not be appropriate, in context of general regulations governing only the civil penalty administrative process in the abstract, to attempt to preclude a subsequent criminal proceeding relating to the conduct which gave rise to the civil proceeding in particular factual circumstance where the criminal action might be warranted, or to attempt to preclude a different sovereign (e.g., state or local government) from taking whatever action it deems warranted in the circumstances.

Another comment suggested that the proposed regulation improperly denies a respondent who is indigent the right to appointed counsel under the Sixth Amendment. We cannot agree that such a right exists in civil penalty proceedings where the maximum penalty which can be assessed is $10,000. It is well established that an indigent's Sixth Amendment right to appointed counsel attaches only in a criminal case where the defendant is subject to a term of imprisonment. *Scott* v. *Illinois*, 440 U.S. 367, 373–74 (1979).

Commenters also questioned the standard of proof applicable to the administrative civil penalty proceedings under which the government must prove its case "by a preponderance of the evidence" (§ 76.2), noting that this was a less stringent standard than that required in the *de novo* district court appeal proceedings under the Act (i.e., proof "beyond a reasonable doubt") and would encourage defendants to seek appeals. One commenter also asserted that the "beyond a reasonable doubt" standard applicable in criminal proceedings was constitutionally required here.

The burden of proof to be used in the civil penalty administrative proceedings is established by the Act, which incorporates certain provisions of the Administrative Procedure Act. See 28 U.S.C. 844a; 5 U.S.C. 554, 556(d); *Steadman* v. *SEC*, 450 U.S. 91, 95–99 (1981). The preponderance of evidence standard is appropriate for these civil administrative proceedings.

An organization commented that sections of the regulations relating to the parties' responsibilities for witness fees and other fees, and the provision allowing the introduction by the government of written statements (see §§ 76.22, 76.25, 76.29) violate a defendant's, particularly an indigent defendant's rights to compulsory process, confrontation, and cross examination under the Sixth Amendment. While this comment is based on a substantial misunderstanding of the regulatory provisions in question, it must be noted again that the constitutional Sixth Amendment rights in question apply to criminal rather than civil proceedings.

Nevertheless, as noted previously, the regulations are intended to be interpreted and applied in a manner that is consistent with controlling legal principles. Thus, while it is well established that written statements (i.e., hearsay) are generally admissible in administrative proceedings, see, *e.g.*, *Richardson* v. *Perales*, 402 U.S. 389 (1971), it is also clear that constitutional due process and the Administrative Procedure Act (5 U.S.C. 555(d)) require that a defendant be given a reasonable opportunity to confront and cross-examine adverse witnesses, and in some circumstances may preclude reliance by the government solely on written statements to support its burden of proof in the administrative proceedings. The regulations were never intended to suggest that the government can rely solely on written hearsay statements of its witnesses and require the defendant to incur the expense of subpoenaing all government witnesses in order to cross-examine those witnesses. Instead, they are intended only to reflect that in some circumstances hearsay statements may be admissible and that generally defendants are responsible for the expenses incurred in presenting a defense.

Because of possible misunderstandings about the intent of the proposed regulations, §§ 76.22, 76.23, 76.25, and 76.29 have been revised slightly to clarify that the government will be expected generally to present its case through the oral testimony of its witnesses, and that in making a determination as to whether written statements may be used in lieu of oral testimony, the Administrative Law Judge must rely on established legal principles. In addition, the final rules clarify that the Administrative Law Judge has authority, in appropriate circumstances, to make such orders as are necessary under other controlling law with respect to the expenses incurred by an indigent defendant.

Another comment suggested that the authorization of summary judgment in § 76.18(b)(12) is inconsistent with a defendant's confrontation and cross-examination rights. This comment is apparently based upon a misunderstanding of the purpose of the summary judgment provision, and its limitations, in the context of the administrative proceedings under the regulations. Summary judgment, either partial or complete, is authorized only where there are no material disputes as to the facts. It is not intended to be used where the defendant denies the allegations of a complaint or properly invokes a privilege, and is not intended to preclude a defendant from challenging the government's evidence through cross-examination where appropriate. There are, however, circumstances where summary judgment procedures may be appropriate, such as where a defendant admits possession of a controlled substance, but disputes only facts relating to the appropriateness of the amount of the penalty.

A number of the comments were generally directed at the proposed provisions of the regulations relating to administrative discovery, prehearing statements and conferences, motions, protective orders, fees and sanctions, which were perceived as excessively complex, burdensome, and costly. These are variously seen as disadvantaging indigent defendants, coercing a respondent into paying a fine rather than incurring the costs of administrative litigation, and serving as a disincentive to the full use of the administrative civil proceedings instead of criminal proceedings or the subsequent *de novo* district court review proceeding authorized by the statute. Commenters suggested that the proposed rules be amended to make the administrative proceedings as inexpensive and open to a respondent as possible so as to encourage the utilization of the administrative penalty procedures instead of district court litigation. In this regard, one commenting organization suggested that the administrative procedures should be made more informal, flexible and favorable to the respondent, using procedures utilized by the Department of Veterans Affairs (formerly Veterans Administration) as a model.

We agree that an important objective of the regulations is the establishment of an efficient adjudicatory mechanism which can be utilized fully by the parties. It is possible that the procedures and standards reflected in the proposed regulations may have the potential to be complex or expensive and to discourage the full use of administrative civil penalty proceedings by defendants. Nevertheless, many of the procedures and standards under the regulations, such as the requirement of a hearing in conformity with the procedures set forth 5 U.S.C. 554 and the application of the "preponderance of evidence standard" at the administrative level with district court review to be based on the "beyond the reasonable doubt standard," are required by the statute. Moreover, the Department believes that, overall, the prehearing and hearing procedures and standards represent a reasonable balancing of the interests in a full and fair opportunity to contest the allegations of a violation of the statute, and the interests in litigation and cost efficiency.

The Department also believes that at least some of the criticisms regarding the complexity and burden engendered by the regulations are based on misperceptions of the manner in which the rules are intended to operate. The rules are written in a flexible manner with substantial discretion placed in the Administrative Law Judge to tailor the actual procedures in each case to the circumstances of that case, with the goals of adjudicating matters as expeditiously and efficiently as possible while ensuring that a defendant receives an opportunity for a full and fair administrative adjudicatory proceeding. See, *e.g.* §§ 76.4(b), 76.11(b) (respondent's right to waive a hearing and either pay a penalty or seek a determination by written motion); § 76.12 (prehearing statement authorized but not required in every case); § 76.19 (discretionary prehearing conferences if Administrative Law Judge finds that proceeding would be expedited); § 76.21 (discovery protective orders). Accordingly, it is not contemplated that every proceeding will or should involve all of the prehearing motions, statements or procedures, including discovery, but instead that the complexity of the proceeding will be directly related to the nature of each case.

Contrary to the suggestion of one commenter, the administrative procedures utilized by the Department of Veterans Affairs (VA) in making disability compensation decisions are not appropriate models for the civil drug penalty regulations. Unlike the civil penalty statute, which clearly contemplates that because of the very nature of the subject matter, the proceedings will be formal and adversarial, the relevant statutes governing VA disability compensation proceedings require that the proceedings be conducted in an informal, nonadversarial manner and that the VA attempt to represent the interests of the veteran. *See generally Walters* v. *National Ass'n of Radiation Survivors,* 473 U.S. 305, 319–34 (1985).

A commenter complained that the sanction for failure to defend in proposed § 76.26 is problematic because of the vagueness of the term "failure to defend" and because such a sanction could be used inappropriately to force a defendant to expend resources on the administrative proceeding. The Department agrees that in the context of these proceedings the term "failure to defend" is not sufficiently precise. Therefore, § 76.26 has been revised to eliminate this provision. Instead, a sanction has been added for the more specific circumstance in which a defendant, without good cause, fails to appear at a hearing.

In addition to the modifications discussed above, the provision in § 76.30(f) regarding the use of grand jury developed evidence has been deleted. The determination of whether particular evidence is grand jury material and whether such evidence may be disclosed in a civil penalty administrative proceeding requires consideration of other controlling legal authority, including Fed. R. of Crim. P. 6(e), and is outside the scope of authority of the Administrative Law Judge in the civil penalty proceedings. Nevertheless, in appropriate circumstances, as authorized by law, evidence which is presented to a grand jury or which was developed through grand jury processes may be disclosed in civil drug penalty proceedings.

Modifications have also been made to the proposed § 76.36 provisions relating to administrative review by the Attorney General in order to alleviate potential confusion regarding the time within which review by a district court must be sought. Under § 76.36, as modified, the decision and order of the Administrative Law Judge becomes the final order of the Attorney General unless a party requests Attorney General review and the Attorney General enters a subsequent order modifying, vacating, adopting or affirming that order within 30 days of the time of the request for review. This change clarifies that the 30 day period in which a respondent may seek district court review runs from the date this final order is entered.

Finally, non-substantive modifications have been made throughout the regulations in response to comments and upon further consideration of the proposed rules by the Department in order to clarify and streamline the procedures for the administrative proceedings.

III. Conclusion

After thorough consideration of all of the comments received and further review of the matter, it has been determined that the regulations, with the modifications discussed above, should be adopted.

IV. Regulatory Impact Analysis

In accordance with 5 U.S.C. 605(b), the Attorney General certifies that the rule will not have a significant economic impact on a substantial number of small entities. This rule will not be a major rule within the meaning of paragraph 1(b) of Executive Order 12291.

List of Subjects in 28 CFR Part 76

Drug traffic control, Drug abuse, Authority delegations (Government agencies), Penalties.

Therefore, by virtue of the authority vested in me by law, including 5 U.S.C. 301, 21 U.S.C. 844a, 875, 876 and 28 U.S.C. 509, 510, and for the reasons discussed in the preamble above, title 28, chapter I, of the Code of Federal Regulations is amended by adding a new part 76 to read as follows:

PART 76—RULES OF PROCEDURE FOR ASSESSMENT OF CIVIL PENALTIES FOR POSSESSION OF CERTAIN CONTROLLED SUBSTANCES

Authority: 5 U.S.C. 301; 21 U.S.C. 844a, 875, 876; 28 U.S.C. 509, 510.

§ 76.1 Purpose.

This part implements section 6486 of the Anti-Drug Abuse Act of 1988 (the Act), 21 U.S.C. 844a. This part establishes procedures for imposing civil penalties against persons who knowingly possess a controlled substance for personal use that is listed in 21 CFR 1316.91(j)(2) in violation of 21 U.S.C. 844a and specifies the appeal rights of persons subject to a civil penalty pursuant to section 6486 of the Act.

§ 76.2 Definitions.

(a) *Act* means the Anti-Drug Abuse Act of 1988, Public Law 100–690.

(b) *Adjudicatory proceeding* means a judicial-type proceeding leading to the formulation of a final order.

(c) *Administrative Procedure Act* means those provisions of the Administrative Procedure Act, as codified, which are contained in 5 U.S.C 551 through 559.

(d) *Attorney General* means the Attorney General of the United States oı his or her designee.

(e) *Department* means the United States Department of Justice.

(f) *Judge* means an Administrative Law Judge appointed pursuant to the provisions of 5 U.S.C. 3105.

(g) *Penalty* means the amount described in 28 CFR 76.3 and includes the plural of that term.

(h) The term *Personal Use Amount* means possession of controlled substances in circumstances where there is no other evidence of an intent to distribute, or to facilitate the manufacturing, compounding, processing, delivering, importing or exporting of any controlled substance. Evidence of personal use amounts shall not include sweepings or other evidence of possession of amounts of a controlled substance for other than personal use. The following criteria shall be used to determine whether an amount of controlled substance in a particular case is in fact a personal use amount. The absence of any of the factors listed in paragraphs (h)(1) through (h)(5) of this section and the existence of the factor in paragraph (h)(6) of this section shall be relevant, although not necessarily conclusive, to establish that the possession was for personal use, and amounts in excess of those listed in paragraph (h)(6) of this section may be determined to be personal use amounts where circumstances indicate possession of the substance without an intent to distribute or to facilitate the manufacturing, compounding, processing, delivering, importing or exporting of the controlled substance.

(1) Evidence, such as drug scales, drug distribution paraphernalia, drug records, drug packaging material, method of drug packaging, drug "cutting" agents and other equipment, that indicates an intent to process, package or distribute a controlled substance;

(2) Other information indicating possession of a controlled substance with intent to distribute;

(3) The controlled substance is related to large amounts of cash or any amount of prerecorded government funds;

(4) The controlled substance is possessed under circumstances that indicate such a controlled substance is a sample intended for distribution in anticipation of a transaction involving large amounts, or is part of a larger delivery; or

(5) Statements by the possessor, or otherwise attributable to the possessor, including statements of co-conspirators, that indicate possession with intent to distribute.

(6) The amounts do not exceed the following:

(i) One gram of a mixture or substance containing a detectable amount of heroin;

(ii) One gram of a mixture or substance containing a detectable amount of—

(A) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivations of ecgonine or their salts have been removed;

(B) Cocaine, its salts, optical and geometric isomers, and salts of isomers;

(C) Ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(D) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (h)(6)(ii) (A) through (C) of this section;

(iii) 1/10 gram of a mixture or substance described in paragraph (h)(6)(ii) of this section which contains cocaine base;

(iv) 1/10 gram of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 500 micrograms of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) One ounce of a mixture or substance containing a detectable among of marijuana;

(vii) One gram of methamphetamine, its salts, isomers, and salts of its isomers, or one gram of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

(i) *United States Attorney* means the United States Attorney in the federal district in which the alleged violation occurred, or his or her designees, or an Assistant Attorney General.

(j) *Commencement of proceeding* is the service upon a respondent of a Notice of Intent to Assess a Civil Penalty.

(k) *Complainant* means the United States.

(l) *Complaint* means the formal document initiating adjudicatory proceedings.

(m) *Consent Order* means any written document containing a specified remedy or other relief agreed to by all parties and entered as an order by the Judge.

(n) *Hearing* means that part of a proceeding which involves the submission of evidence, either by oral presentation or written submission.

(o) *Motion* means an oral or written request, made by a person or party, for some action by a Judge.

(p) *Order* means the whole or any part of a final procedural or substantive disposition of a matter by the Judge.

(q) *Party* includes the United States of America and any person named as a respondent.

(r) *Respondent* means any person alleged in a Notice of Intent to Assess a Civil Penalty or Complaint under 28 CFR 76.4 and 76.5 to be liable for a civil penalty under 28 CFR 76.3.

§ 76.3 Basis for civil penalty.

(a) Any individual who knowingly possesses a controlled substance that is listed in § 76.2(h) in violation of 21 U.S.C. 844a shall be liable to the United States for a civil penalty in an amount not to exceed $10,000 for such violation.

(b) The income and net assets of an individual shall not be relevant to the determination whether to assess a civil penalty under this part or to prosecute the individual criminally. However, if a decision is made to assess a civil penalty, the income and net assets of an individual shall be considered in determining the amount of a penalty under this part.

(c) A civil penalty may not be assessed under this part if the individual previously was convicted of a federal or state offense relating to a controlled substance as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(d) A civil penalty may not be assessed on an individual under this part on more than two separate occasions.

(e) A civil penalty under this part may be assessed by the Attorney General only after an order has been issued on the record and after an opportunity for a hearing has been given in accordance with 5 U.S.C. 554. The Attorney General by and through the United States Attorney having jurisdiction over the matter shall provide written notice to the individual who is the subject of the proposed order informing the individual of the opportunity to receive such a hearing with respect to the proposed order. The hearing may be held only if the individual makes a request for the hearing before the expiration of the thirty (30) day period beginning on the date such notice is served.

§ 76.4 Enforcement procedures.

(a) *Commencement of proceedings.* If the United States Attorney's office having jurisdiction over the matter determines that a person has violated section 6486 of the Act, the proceeding to assess a civil penalty under section 6486 of the Act shall be commenced by the United States Attorney issuing a Notice of Intent to Assess Civil Penalty. Service of this Notice shall be accomplished pursuant to 28 CFR 76.6.

(b) *Notice of intent to assess a civil penalty.* The Notice of Intent to Assess Civil Penalty (Notice) will contain a concise statement of factual allegations informing the respondent of the act or conduct alleged to be in violation of law, the statutory and regulatory provisions alleged to have been violated, and the amount of penalty for which the respondent could be liable. The Notice will advise the respondent of the following, in addition to any other specific information determined by the United States Attorney to be necessary:

(1) That the respondent has the right to representation by counsel, but not at government expense;

(2) That any statement given during the course of the proceeding may be used against the person in this or any other proceeding, including any criminal prosecution;

(3) That a respondent may be able to assert a privilege, such as the privilege against self-incrimination;

(4) That failure to file a response to the allegations listed in the Notice within thirty (30) days of the date of service may result in the entry of a non-appealable final order assessing a penalty in an amount to be determined by the Attorney General;

(5) That the respondent has the right to request an adjudicatory proceeding, including a hearing, before a Judge pursuant to 5 U.S.C. 554–557 and this part, and that such request, in accordance with paragraph (c) of this section, must be made within thirty (30) days from the date the notice is served;

(6) That a respondent may waive an adjudicatory proceeding at any time and agree to pay a penalty in an amount to be determined by the Attorney General; and

(7) That in determining the amount of the penalty the respondent's income and net assets must be considered.

(c) *Answer to notice.* To timely request an adjudicatory proceeding in response to a Notice, a respondent must serve upon the United States Attorney designated in the Notice a written answer responding to each allegation listed in the Notice and request a hearing, in accordance with 28 CFR 76.4(b), within thirty (30) days from the date the Notice was served upon the respondent. If the respondent does not serve an answer within thirty (30) days, the Attorney General or his designee may enter a final order, from which there is no appeal, ordering a payment of a civil penalty.

§ 76.5 Complaint.

(a) If the respondent requests an adjudicatory proceeding, the United States Attorney, within fifteen (15) days after receipt of the request, shall file a complaint against the respondent with a Judge who has been assigned to hear and decide the case and shall serve a copy of the complaint on the respondent as provided in 28 CFR 76.6(b).

(b) The complaint shall contain a concise statement of factual allegations informing the respondent of the act or conduct alleged to be in violation of law, the approximate date, place and location of the alleged violation including the federal district, the statutory provisions alleged to have been violated, the amount of penalty for which the respondent could be held liable, and the amount of the proposed penalty. It shall also indicate the date upon which the Notice of Intent to Assess Civil Penalty was served and shall be accompanied by a copy of that notice.

§ 76.6 Service and filing of documents.

(a) *Generally.* Unless ordered otherwise, an original and one copy of the complaint and all other pleadings shall be filed with the Judge who has been assigned to the case. Each party shall deliver or mail, in accordance with paragraph (b) of this section, a copy of all pleadings, including any attachments to the other party. Each pleading filed shall be clear and legible.

(b) *By and on parties.* The Notice of Intent to Assess Civil Penalty and the Complaint shall be served by personal delivery or by certified or registered mail, return receipt requested, to the respondent. When it is known that a party is represented by an attorney, service of any other pleading, paper or document subsequent to the Notice and Complaint shall be made upon the party's attorney. Service of such other pleadings, papers, or documents may be made by personal delivery or by mailing, by first class mail, a copy to the party or attorney at the party's or attorney's last known address. The party serving the document shall certify the manner and date of service.

(c) *By the Judge.* Except as provided in paragraph (d) of this section, service of Notices, Orders and Decisions shall be made by first class mail to the last known address of a party or, if the party is known to be represented by an attorney, to the attorney.

(d) *Service of Notice of Hearing.* Service of Notice of the Date Set for Hearing shall be made by the Judge with whom the complaint has been filed either by delivering a copy to the individual party or, if known, to the attorney of record of a party; or by mailing, by certified or registered mail, return receipt requested, a copy to the last known address of a party or a party's attorney.

(e) Service is complete upon delivery to the addressee or, in the case of service by mail, upon mailing.

(f) Filing of pleadings, papers or other documents shall be deemed completed upon delivery to the Judge assigned to the case or the Judge's designee.

§ 76.7 Content of pleadings.

(a) Every pleading shall contain a caption setting forth the statutory provision under which the proceeding is instituted, the title of the proceeding, the docket number assigned by the Judge, the names of all parties, and a designation of the type of pleading or paper (e.g., complaint, motion to dismiss). The pleading shall be signed and shall contain the address and telephone number of the party or person representing the party. The pleadings should be typewritten when possible on standard-size (8½ x 11) paper. Legal size (8½ x 14) paper will not be accepted, except upon approval by the Judge.

(b) Illegible documents, whether handwritten, typewritten, photocopied, or otherwise, will not be accepted. Papers may be reproduced by any duplicating process, provided all copies are clear and legible.

(c) All documents presented by a party in a proceeding must be in English or, if in a foreign language, accompanied by a certified translation.

§ 76.8 Time computations.

(a) *Generally.* In computing any period of time under this part or in an order issued hereunder, the time begins with the day following the act, event, or default requiring service, and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the federal government, in which case the time period includes the next business day. When the period of time prescribed is eleven (11) days or less, intermediate Saturdays, Sundays, and holidays shall be excluded in the computation.

(b) *Date of entry of orders.* In computing any period of time involving the date of the entry of an order, the date of entry shall be the date the order is signed by the Judge.

(c) *Computation of time for service by mail.* Whenever a party has a right or is required to do some act or take some action within a prescribed period after service of a pleading, paper, or notice and the pleading, paper, or notice is served upon the party by mail, three (3) days shall be added to the prescribed period.

§ 76.9 Responsive pleading—answer.

(a) *Time for answer.* A respondent shall file and serve on the United States Attorney having jurisdiction over the matter an answer within thirty (30) days after the service of a complaint.

(b) *Default.* Failure of the respondent to file and serve an answer within the time provided shall be deemed to constitute a waiver of his or her right to appear and contest the allegations of the complaint. In such cases, the Judge may enter a judgment by default.

(c) *Answer.* Any respondent contesting any material fact alleged in a complaint, or contending that he or she is entitled to judgment as a matter of law, shall file an answer in writing.

(1) The answer shall include a statement of the facts supporting each affirmative defense.

(2) The answer shall include a statement that the respondent admits,

denies, does not have and is unable to obtain sufficient information to admit or deny each allegation, or that an answer to the allegation is protected by a privilege, including the privilege against self-incrimination.

(3) A statement of lack of information or a statement that the answer to the allegation is privileged shall have the effect of a denial.

(4) Any allegation not denied shall be deemed to be admitted.

(d) *Reply.* A complainant may file a reply responding to each affirmative defense arrested if the Judge, pursuant to 28 CFR 76.10, so provides.

(e) *Amendments and supplemental pleadings.* If it will facilitate resolution of the controversy, the Judge may, upon such conditions as are necessary to avoid prejudicing the public interest and the rights of the parties, allow appropriate amendments to complaints and other pleadings at any time prior to the issuance of the Judge's order based on the complaint. When issues not raised by the pleadings are reasonably within the scope of the original complaint and are tried by express or implied consent of the parties, they shall be treated in all respects as if they had been raised in the pleadings, and such amendments may be made as necessary to make the pleadings conform to the evidence. The Judge may, upon reasonable notice and such terms as are just, permit supplemental pleadings setting forth transactions, occurrences, or events which have happened or new law promulgated since the date of the pleadings and which are relevant to any of the issues involved.

§ 76.10 Motions and requests.

(a) *Generally.* Any application for an order or any other request shall: be made by motion which shall be in writing (unless the Judge in the course of an oral hearing or appearance consents to accept such motion orally), state with particularity the grounds therefor, and set forth the relief or order sought. Motions or requests made during the course of any oral hearing or appearance before a Judge may be stated orally or in writing and made part of the transcript. All parties shall be given reasonable opportunity to respond or object to the motion or request.

(b) *Responses to motions.* Within ten (10) days after a written motion is served, or within such other period as the Judge may fix, the other party to the proceeding may file a response to the motion, accompanied by such affidavits or other evidence as the party desires to rely upon. Unless the Judge provides otherwise, no reply to a response shall be filed.

(c) *Oral arguments or briefs.* No oral argument will be heard on motions unless the Judge otherwise directs. Written memoranda or briefs may be filed with motions or responses to motions, stating the points and authorities relied upon in support of the position taken.

§ 76.11 Notice of hearing.

(a) When the Judge receives the complaint and answer, the Judge shall cause to be served a Notice of Hearing upon the parties in the manner prescribed by 28 CFR 76.6(d).

(b) Such notice shall include:

(1) The time and place and nature of the hearing. In fixing the time and place of the hearing, the Judge will attempt to minimize the costs to the parties;

(2) The legal authority and jurisdiction under which the hearing is to be held;

(3) The description of the procedures for the conduct of the hearing;

(4) A notice that the respondent party may waive the right to an oral hearing and request that the matter be determined on written motions and written submission of the evidence; and

(5) Such other matters as the Judge deems appropriate.

§ 76.12 Prehearing statements.

(a) At any time prior to the commencement of the hearing, the Judge may order any party to file a prehearing statement of position.

(b) A prehearing statement shall state the name of the party on whose behalf it is presented and shall briefly set forth the following matters, unless otherwise ordered by the Judge:

(1) Issues involved in the proceedings and whether the respondent requests an oral hearing;

(2) Facts stipulated;

(3) Facts in dispute;

(4) Witnesses, except to the extent that disclosure would be privileged, and exhibits by which disputed facts will be litigated;

(5) A brief statement of applicable law;

(6) The conclusions to be drawn;

(7) The estimated time required for presentation of the party's case; and

(8) Any appropriate comments, suggestions, or information which might assist the parties or the Judge in preparing for the hearing or otherwise aid in the disposition of the proceeding.

§ 76.13 Parties to the hearing.

The parties to the hearing shall be the United States of America and the respondent.

§ 76.14 Separation of functions.

An employee or an agent of the Department who is or was engaged in investigative or prosecutive functions for or on behalf of the United States in a case may not participate in the decision of that case.

§ 76.15 Ex parte communications.

(a) *Generally.* The Judge shall not consult with any party, attorney or person (except persons in the office of the Judge) on any legal or factual issue unless upon notice and opportunity for all parties to participate. No party or attorney representing a party shall communicate in any instance with the Judge on any matter at issue in a case, unless notice and opportunity has been afforded for the other party to participate. This provision does not prohibit a party or attorney from inquiring about the status of a case or asking questions concerning administrative functions or procedures.

(b) *Sanctions.* A party or participant who makes a prohibited *ex parte* communication, or who encourages or solicits another to make any such communication, may be subject to any appropriate sanctions. An attorney who makes a prohibited *ex parte* communication, or who encourages or solicits another to make any such communication, may be subject to sanctions, including, but not limited to, exclusion from the proceedings.

§ 76.16 Disqualification of a Judge.

(a) When a Judge deems himself or herself disqualified to preside in a particular proceeding, such Judge shall withdraw therefrom by notice on the record directed to the Chief Administrative Hearing Officer for the district in which the case is brought or, if there is no Chief Administrative Hearing Officer, to the Attorney General.

(b) Whenever any party shall deem the Judge for any reason to be disqualified to preside, or to continue to preside, in a particular proceeding, that party shall file with the Judge a motion to recuse. The motion shall be supported by an affidavit setting forth the alleged grounds for disqualification. The Judge shall rule upon the motion.

(c) In the event of disqualification or recusal of a Judge as provided in paragraph (a) or (b) of this section, the Chief Administrative Hearing Officer or the Attorney General shall refer the matter to another Judge for further proceedings.

(d) If the Judge denies a motion to disqualify, the Attorney General may determine the matter only as part of the

Attorney General's review of the initial decision on appeal, if any.

§ 76.17 Rights of parties.

Except as otherwise limited by this Part, all parties may:

(a) Be represented, advised and accompanied by an attorney at law who is a member in good standing of the bar of the District of Columbia or of any state, territory or commonwealth of the United States;

(b) Participate in any conference held by the Judge;

(c) Conduct discovery in accordance with 28 CFR 76.18 and 76.21;

(d) Agree to stipulations of fact or law, which shall be made part of the record;

(e) Present evidence relevant to the issues at the hearing;

(f) Present and cross-examine witnesses;

(g) Present oral argument at the adjudicatory proceeding as permitted by the Judge; and

(h) Submit a written brief and a proposed final order after the hearing.

§ 76.18 Authority of the Judge.

(a) The Judge shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The Judge has the authority to:

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas in accordance with 21 U.S.C. 875 and 876 requiring the attendance of witnesses and the production of documents at dispositions or at hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery;

(8) Regulate the course of the hearing and the conduct of representatives and parties;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(13) Conduct any conference, argument, or hearing on motions in person or by telephone; and

(14) Exercise such other authority as necessary to carry out the responsibilities of the Judge under this Part.

(c) The Judge does not have the authority to rule upon the validity of federal statutes or regulations.

§ 76.19 Prehearing conferences.

(a) *Purpose and scope.* Upon motion of a party or in the Judge's discretion, the Judge may direct the parties or their counsel to participate in a prehearing conference at any reasonable time prior to a hearing, or during the course of a hearing, when the Judge finds that the proceeding would be expedited by such a conference. Prehearing conferences normally shall be conducted by telephone unless, in the opinion of the Judge, such method would be impractical, or when such conferences can be conducted in a more expeditious or effective manner by correspondence or personal appearance. Reasonable notice of the time, place, and manner of the prehearing conference shall be given. At the conference, the following matters may be considered:

(1) The simplification of issues;

(2) The necessity of amendments to pleadings;

(3) The possibility of obtaining stipulations of facts and of the authenticity, accuracy, and admissibility of documents, which will avoid unnecessary proof;

(4) The limitations on the number of expert or other witnesses;

(5) Negotiation, compromise, or settlement of issues;

(6) The exchange of copies of proposed exhibits;

(7) The identification of documents or matters of which official notice may be required;

(8) A schedule to be followed by the parties for completion of the actions decided at the conference; and

(9) Such other matters, including the disposition of pending motions and resolution of issues regarding the admissibility of evidence, as may expedite and aid in the disposition of the proceeding.

(b) *Reporting.* A verbatim record of the conference shall not be kept unless directed by the Judge.

(c) *Order.* Actions taken as a result of a prehearing conference shall be reduced to a written order unless the Judge concludes that a stenographic report shall suffice or, if the conference takes place within seven (7) days of the beginning of a hearing, and the Judge elects to make a statement on the record at the hearing summarizing the actions taken.

§ 76.20 Consent Order or settlement prior to hearing.

(a) *Generally.* At any time after the commencement of a proceeding, the parties jointly may move to defer the hearing for a reasonable time to permit negotiation of a settlement or an agreement containing findings and an order disposing of the whole or any part of the proceeding. The allowance of such deferment and the duration thereof shall be at the discretion of the Judge, after consideration of such factors as the nature of the proceeding, the requirements of the public interest, the representations of the parties, and the probability of reaching an agreement which will result in a just disposition of the issue involved. The Judge may require the parties to submit progress reports on a regular basis as to the status of negotiations.

(b) *Consent orders.* Any agreement containing consent findings and an order disposing of a proceeding or any part thereof shall also provide:

(1) That the order shall have the same force and effect as an order made after full hearing;

(2) That the entire record on which any order may be based shall consist solely of the complaint or notice of administrative determination (or amended notice, if one is filed), as appropriate, and the agreement;

(3) A waiver of any further procedural steps before the Judge; and

(4) A waiver of any right to challenge or contest the validity of the order entered into in accordance with the agreement.

(c) *Submission.* On or before the expiration of the time granted for negotiations, the parties or their counsel may:

(1) Submit the proposed agreement containing consent findings and an order for consideration by the Judge; or

(2) Notify the Judge that the parties have reached a full settlement and have agreed to dismissal of the action; or

(3) Inform the Judge that agreement cannot be reached.

(d) *Disposition.* In the event that an agreement containing consent findings and an order is submitted, the Judge, within thirty (30) days or as soon as practicable thereafter may, if satisfied with its timeliness, form, and substance, accept such agreement by issuing a decision based upon the agreed findings. The Judge has the discretionary authority to conduct a hearing to determine the fairness of the agreement, consent findings, and proposed order.

§ 76.21 Discovery.

(a) *Scope.* Discovery under this Part covers any matter not otherwise privileged or protected by law, which is directly relevant to the issues involved in the case, including the existence, description, nature, custody, condition, and location of documents or other tangible things, and the identity and location of persons having knowledge of relevant facts. To the extent not inconsistent with this part, the Federal Rules of Civil Procedure may be used as a general guide for discovery practices in proceedings before the Judge. However, unless otherwise stated in this part, the Federal Rules shall be deemed to be instructive rather than controlling.

(b) *Methods.* Discovery may be obtained by one or more of the methods provided under the Federal Rules of Civil Procedure, including: written interrogatories, depositions, requests for production of documents or things for inspection or copying, and requests for admission addressed to parties.

(c) *Procedures governing discovery*—(1) *Discovery from a party.* A party seeking discovery from another party shall initiate the process by serving a request for discovery on the other party. The request for discovery shall:

(i) State the time limit for responding, as prescribed in 28 CFR 76.21(c)(4);

(ii) In the case of a request for a deposition of a party or an employee of a party shall

(A) specify the time and place of the taking of the deposition, and

(B) be served on the person to be deposed.

(2) *Discovery from a nonparty.* Whenever possible, a party seeking a deposition and/or production of documents from a nonparty shall attempt to obtain the nonparty's voluntary cooperation. A party seeking such discovery from a nonparty may initiate such discovery by serving a request for discovery on the nonparty directly and by serving the other party. Upon failure to obtain voluntary cooperation, discovery from a nonparty may be sought by a written motion directed to the Judge in accordance with paragraph (c)(3) of this section.

(3) *Discovery motions.* (i) A party shall answer a discovery request within the time provided by 28 CFR 76.21(c)(4), either by furnishing to the requesting party the information or testimony requested, agreeing to make deponents available to testify within a reasonable time, or by stating an objection to the particular request and the reasons for objection. Upon the failure of a party to respond in full to a discovery request, the requesting party may file with the Judge a motion to compel. A copy of the motion shall be served on the other party. The motion shall be accompanied by:

(A) A copy of the original request and a statement showing the relevance and materiality of the information sought; and

(B) A copy of the objections to discovery or, where appropriate, a statement with accompanying affidavit that no response has been received.

(ii) If a nonparty will not voluntarily respond to a discovery request in full, the requesting party may file with the Judge a written motion seeking a subpoena. A copy of the motion shall be served on the other party in accordance with 28 CFR 76.23. The motion shall be accompanied by:

(A) A copy of the original request and a statement showing the relevance, materiality and reasonable scope of the information sought;

(B) A copy of the objections to discovery or, where appropriate, a statement with accompanying affidavit that no response has been received; and

(C) In the case of a deposition, the date, time, and place of the proposed deposition.

(iii) The other party may respond to a motion to compel discovery or for issuance of a subpoena requiring a deposition or production of documents under this section by filing an opposition and/or a motion for a protective order in accordance with 28 CFR 76.24 within the time limits set forth in paragraph (c)(4)(iv) of this section.

(4) *Time limits.* (i) Discovery may be initiated after the filing of a complaint and shall be completed within the time designated by the Judge, but no later than seventy-five (75) days after the filing of the answer, unless a different time limit is set by the Judge after due consideration of the particular situation, including the dates set for hearing.

(ii) A party or nonparty shall file and serve a response to a discovery request promptly, but not later than twenty (20) days after the date of service of the request or order of the Judge.

(iii) A motion seeking a subpoena for the deposition testimony of a nonparty or for the production of documents by a nonparty, or a motion for an order compelling discovery from a party, shall be filed with the Judge and served upon the other party within ten (10) days of the date of service of objections, or within ten (10) days of the expiration of the time limit for response when no response is received, unless otherwise ordered by the Judge.

(iv) An opposition to a motion to compel, an opposition to a motion for an order to depose a nonparty or for the production of documents by a nonparty, or a motion for a protective order must be filed with the Judge and served upon the other party within ten (10) days of the date of service of the motion to which such motion relates.

(5) *Orders for discovery.* (i) Any order issued compelling discovery shall include, as appropriate:

(A) Provision for notice to the person to be deposed as to the time and place of such deposition;

(B) Such conditions or limitations concerning the conduct or scope of the discovery or the subject matter of the discovery as may be necessary to prevent undue delay or to protect a party or other individual or entity from undue expense, embarrassment or oppression;

(C) Limitations upon the time for conducting depositions, answering written interrogatories, or producing documentary evidence; and

(D) Other restrictions upon the discovery process as determined by the Judge.

(ii) The order will be served on the parties by the Judge, together with a subpoena, if approved in the case of discovery sought from nonparties, directed to the individual or entity from which discovery is sought, specifying the manner and time limit for compliance. It shall be the responsibility of the party seeking discovery from a nonparty to serve or arrange for service of an approved discovery request and subpoena on the nonparty from whom discovery is sought and on the other party.

(iii) Failure to comply with an order compelling discovery may subject the noncomplying party to sanctions under 28 CFR 76.26.

(6) *Costs.* Each party shall bear its own costs of discovery unless otherwise agreed by the parties or ordered by the Judge. The party seeking the deposition shall provide for a verbatim transcript of the description, which shall be available to all parties for inspection and copying.

§ 76.22 Exchange of witness lists, statements and exhibits.

(a) At least twenty-one (21) days before the hearing or at such other time as may be ordered by the Judge, the parties shall exchange witness lists, copies of prior statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the respondent intends to offer in lieu of live testimony in accordance with 28 CFR 76.29. At the time these documents are exchanged, any party that intends to rely on the transcript of deposition testimony in lieu of live testimony at the hearing, if permitted by the Judge, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.

(b) If a party objects to admission, the Judge may not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above unless the Judge finds good cause for the failure and that there is no prejudice to the objecting party.

(c) Unless a party objects within the times set by the Judge, documents exchanged in accordance with paragraph (a) of this section shall be deemed to be authentic for the purpose of admissibility at the hearing.

§ 76.23 Subpoenas.

(a) Requests for the issuance of subpoenas requiring the attendance and testimony of witnesses or the production of documents or other evidence under 21 U.S.C. 875 and 876 shall be filed with the Judge. Subpoenas are not ordinarily required to obtain the attendance of federal employees as witnesses, but such testimony shall be sought first by filing a request with the United States Attorney.

(b) Requests for subpoenas shall be filed with the Judge in writing and shall specify with particularity the books, papers, or testimony desired, supported by a showing of general relevance and reasonable scope, and a statement of the facts expected to be proven thereby. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses or documents to be found.

(c) A party seeking a subpoena for the attendance of a witness at a hearing shall file a written request therefor not less than fifteen (15) days before the date fixed for the hearing unless otherwise allowed by the Judge upon a showing of good cause.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) Unless otherwise ordered by the Judge, the party seeking the subpoena is responsible for service of the subpoena. A subpoena may be served by any person at least eighteen (18) years of age who is not a party, including a private process server or other person authorized to serve process in actions brought in state courts of general jurisdiction or in Federal courts. Service shall be by personal delivery. Proof of service shall be made by affidavit of the person serving a subpoena entered on a true copy of the subpoena.

(f) A party or the individual to whom the subpoena is directed may file with the Judge a motion to quash the subpoena within ten (10) days after service of the subpoena, or on or before the time specified in the subpoena for compliance if it is less than ten (10) days after service.

(g) Upon failure of any person to comply with a subpoena issued by the Judge, the Attorney General, in the name of the Judge, but on relation of the party, shall institute proceedings in the appropriate district court for the enforcement of the subpoena, unless the enforcement of the subpoena would be inconsistent with law. Neither the Attorney General nor the Judge shall be deemed thereby to have assumed responsibility for prosecution of the same before the court.

§ 76.24 Protective Order.

(a) A party or a prospective witness or deponent may seek to limit the availability or disclosure of evidence by filing a motion for a protective order with respect to discovery sought by an opposing party or with respect to the hearing.

(b) In issuing a protective order, the Judge may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, or to protect privileged information including one or more of the following orders:

(1) That the discovery not be had;

(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;

(3) That the discovery may be had only through a method of discovery other than that requested;

(4) That certain matters not be the subject of inquiry, or that the scope of discovery be limited to certain matters;

(5) That discovery be conducted with no one present except persons designated by the Judge;

(6) That the contents of discovery or evidence be sealed;

(7) That a sealed deposition be opened only by order of the Judge;

(8) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the Judge.

§ 76.25 Fees.

Unless otherwise ordered by the Judge, the party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed. Such costs shall be in the amounts that would be payable to a witness in a proceeding in United States district court. A check for witness fees and mileage shall accompany the subpoena when served, except that when a subpoena is issued on behalf of the complainant, a check for witness fees and mileage need not accompany the subpoena.

§ 76.26 Sanctions.

(a) As necessary to meet the ends of justice, the Judge may impose sanctions upon any party or a party's counsel, including, but not limited to sanctions based upon the following reasons:

(1) Failure to comply with an order, rule, or procedure governing the proceeding;

(2) Failure to prosecute an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the proceeding.

(b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition, the production of evidence within the party's control, or a request for admission the Judge may, as appropriate under law:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission as to unprivileged matters, deem admitted each matter of which an admission is requested;

(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought;

(4) Strike any appropriate part of the pleadings or other submissions of the party failing to comply with such order; and

(5) Permit the requesting party to introduce secondary evidence concerning the information sought.

(d) If a party fails to prosecute an action under this Part commenced by service of a notice of hearing, the Judge may dismiss the action.

(e) If a respondent who has requested a hearing pursuant to 28 CFR 76.4, and who has been served with a Notice of a Hearing under 28 CFR 76.6, fails to appear at the hearing, absent good cause shown by the respondent, the Judge may issue an initial decision imposing a penalty.

(f) The Judge may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

§ 76.27 The hearing and burden of proof.

(a) The Judge shall conduct a hearing on the record in order to determine whether the respondent is liable for a civil penalty under 28 CFR 76.3 and, if so, the appropriate amount of any such civil penalty, considering the income and net assets of the respondent.

(b) The United States Attorney shall prove respondent's liability and appropriateness of the amount of the penalty by a preponderance of the evidence.

(c) The respondent shall prove any affirmative defenses by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise closed by the Judge for good cause shown.

§ 76.28 Location of hearing.

The hearing shall be held in the judicial district of the United States Attorney's Office having jurisdiction over the matter.

§ 76.29 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the Judge and to the extent otherwise permitted by law, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties, along with the last known address of such witness, in a manner which allows sufficient time for other parties to subpoena, if necessary, such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing and deposition transcripts shall be exchanged as provided in 28 CFR 76.22.

(c) The Judge shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth;

(2) Avoid needless consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The Judge shall permit the parties to conduct such cross-examination as may be required for a full and true disclosure of the facts.

(e) At the discretion of the Judge, a witness may be cross-examined on matters relevant to the proceeding without regard to the scope of his or her direct examination.

(f) Upon motion of any party, the Judge shall order witnesses excluded so that they cannot hear the testimony of other witnesses. This part does not authorize exclusion of the following:

(1) The respondent;

(2) An individual whose presence is shown by a party to be essential to the presentation of its case.

§ 76.30 Evidence.

(a) The Judge shall determine the admissibility of evidence.

(b) Except as provided in this part, the Judge shall not be bound by the Federal Rules of Evidence. However, the Judge may apply the Federal Rules of Evidence where appropriate, e.g., to exclude unreliable evidence.

(c) The Judge shall exclude irrelevant and immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Relevant evidence may be excluded if it is privileged under federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The Judge shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the Judge pursuant to 28 CFR 76.27.

§ 76.31 Standards of conduct.

(a) All persons appearing in proceedings before a Judge are expected to act with integrity and in an ethical manner.

(b) The Judge may exclude parties, witnesses, and their attorneys for refusal to comply with directions, continued use of dilatory tactics, refusal to adhere to reasonable standards of orderly and ethical conduct, failure to act in good faith, or violation of the prohibition against *ex parte* communications. The Judge shall state in the record the cause for suspending or barring an attorney from participation in a proceeding. Any attorney so suspended or barred may appeal to the Chief Administrative Hearing Officer for the District, or if there is no Chief Administrative Hearing Officer, to the Attorney General but no proceeding shall be delayed or suspended pending disposition of the appeal; provided, however, that the Judge shall suspend the proceeding for a reasonable time for the purpose of enabling the party to obtain another attorney.

§ 76.32 Hearing room conduct.

Proceedings shall be conducted in an orderly manner. The consumption of food or beverage, smoking, or rearranging of courtroom furniture, unless specifically authorized by the Judge, is prohibited.

§ 76.33 Legal assistance.

The Judge does not have authority to appoint counsel, nor can it refer a party to an attorney.

§ 76.34 Record of hearings.

(a) General. Unless otherwise agreed by the parties, a verbatim written record of all hearings shall be kept. All evidence upon which the Judge relies for decision shall be contained in the transcript of testimony, either directly or by appropriate reference. All exhibits introduced as evidence shall be marked for identification and incorporated into the record. Upon completion of the transcript, the transcript shall be filed by the official court reporter with the Judge, who will notify the parties. Transcripts may be obtained by the parties and the public from the official court reporter of record. Unless otherwise ordered by the Judge, any fees in connection therewith shall be the responsibility of the parties.

(b) Corrections. Corrections to the official transcript will be permitted upon motion. Motions for corrections must be submitted within ten (10) days of the service by the Judge of the notice of the filing of the transcript, or such other time as may be permitted by the Judge. Corrections of the official transcript will be permitted only when errors of substance are involved and only upon approval of the Judge.

(c) The record of the proceedings shall consist of the notices, pleadings, motions, rulings, exhibits, orders, the findings, decisions or opinions of the Judge, the stipulations and briefs, and the transcript(s) of the hearing(s).

§ 76.35 Decision and Order of the Judge.

(a) *Proposed Decision and Order.* Within twenty (20) days of the filing of the transcript of the testimony, or such additional time as the Judge may allow, a party, if authorized by the Judge, may file proposed Findings of Fact, Conclusions of Law, and Order together with a supporting brief expressing the reasons for such proposals. Such proposals and briefs shall be served on all parties, and shall refer to all portions of the record and to all authorities relied upon in support of each proposal.

(b) *Decision.* Within a reasonable time, but not later than forty-five (45) days after the filing of the hearing transcript, and the time allowed for the filing of the post-hearing briefs, proposed Findings of Fact, Conclusions of Law, and Order, if any, or within thirty (30) days after receipt of an agreement containing Consent Findings and Order disposing of the disputed matter in whole, the Judge shall make a decision. The decision of the Judge shall include Findings of Fact and Conclusions of Law upon each material issue of fact or law presented on the record. The decision of the Judge shall be based upon the whole record. It shall be supported by reliable and probative evidence. The standard of proof shall be a preponderance of the evidence. Such decision shall be in accordance with the regulations and the statutes conferring jurisdiction. If the Judge fails to meet the deadline contained in this paragraph, he or she shall notify the parties and the Attorney General of the reason for the delay and shall set a new deadline.

(c) *Order.* If the Judge determines, by a preponderance of the evidence, that the respondent knowingly possessed a controlled substance that is listed in section 401(b)(1)(A) of the Controlled Substances Act (21 U.S.C. 841(b)) in violation of 21 U.S.C. 844, in an amount that, as specified by this part, is a personal use amount, the order shall require the respondent to pay a civil penalty of not more than $10,000 for each violation. If the Judge determines that a preponderance of the evidence does not establish that the respondent knowingly possessed a controlled substance as described above, for his or her personal use, then the order shall dismiss the complaint. A copy of the decision and order together with a record of the proceedings will be forwarded to the Attorney General.

§ 76.36 Administrative and judicial review.

(a) Upon entry of an order by a Judge, any party may file with the Attorney General, within ten (10) days of the date of the Judge's decision and order, a written request for review of the decision and order together with supporting arguments. Within thirty (30) days from the date of the filing of the request for review, the Attorney General may enter an order which adopts, affirms, modifies or vacates the Judge's order.

(b) If a party does not seek review of the Judge's decision, or if the Attorney General enters no order within thirty (30) days from the date of the filing of the request for review, the order of the Judge becomes the final order of the Attorney General. If the Attorney General modifies or vacates the order, the order of the Attorney General becomes the final order.

(c) An individual subject to an order assessing a penalty after a hearing may, before the expiration of the thirty (30) day period beginning on the date the final order is entered, either by the Judge or the Attorney General, whichever is applicable, bring a civil action in the appropriate District Court of the United States pursuant to the provisions of 21 U.S.C. 844a(g) and obtain *de novo* judicial review of the final order.

§ 76.37 Collection of civil penalties.

(a) Collection of any penalty shall be the responsibility of the United States Attorney having jurisdiction over the matter.

(b) The United States Attorney having jurisdiction over the matter may commence a civil action in any appropriate district court of the United States for the purpose of recovering the amount assessed and an amount representing interest at a rate computed in accordance with 28 U.S.C. 1961.

§ 76.38 Deposit in the United States Treasury.

All amounts collected pursuant to this Part shall be deposited as miscellaneous receipts in the United States Treasury.

§ 76.39 Compromise or settlement after Decision and Order of a Judge.

(a) The United States Attorney having jurisdiction over the case may, at any time before the Attorney General issues an order, compromise, modify, or remit, with or without conditions, any civil penalty imposed under this section.

(b) Any compromise or settlement must be in writing.

§ 76.40 Records to be public.

All documents contained in the records of formal proceedings for imposing a penalty under this Part may be inspected and copied, unless ordered sealed by the Judge.

§ 76.41 Expungement of records.

(a) The Attorney General shall expunge all official Department records created pursuant to this Part upon application of a respondent at any time after the expiration of three (3) years from the date of the final order of assessment if:

(1) The respondent has not previously been assessed a civil penalty under this section;

(2) The respondent has paid the penalty;

(3) The respondent has complied with any conditions imposed by the Attorney General;

(4) The respondent has not been convicted of a federal or state offense relating to a controlled substance as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802); and

(5) The respondent agrees to submit to a drug test, and such test shows the individual to be drug free.

(b) A non-public record of a disposition under this Part shall be retained by the Department solely for the purpose of determining in any subsequent proceeding whether the person qualifies for a civil penalty or expungement under this Part.

(c) If a record is expunged under this Part, the individual for whom such an expungement was made shall not be held guilty of perjury, false swearing, or making a false statement by reason of his failure to recite or acknowledge a proceeding under this Part or the results thereof in response to an inquiry made of him for any purpose.

§ 76.42 Limitations.

No action under this Part shall be entertained unless commenced within five (5) years from the date on which the violation occurred.

Dated: December 26, 1990.

Dick Thornburgh,

Attorney General.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 920

Maryland Regulatory Program; Permitting; Performance Standards; Bond Forfeiture

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendments.

SUMMARY: OSM is announcing the approval of proposed amendments of the Maryland regulatory program (hereinafter referred to as the Maryland program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendments modify 11 sections in the Code of Maryland Administrative Regulations (COMAR) and are intended to make the State's regulations consistent with the