Sunshine Act Meetings

Federal Register
Vol. 57, No. 165
Tuesday, August 25, 1992

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

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

TIME AND DATE: 10:00 a.m., Thursday, August 27, 1992.

PLACE: Room, 600, 1730 K Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument on the following:

1. *Southern Ohio Coal Co.*, Docket No. LAKE 91-650-R, etc. (Issues include whether the judge erred in concluding that Southern Ohio Coal Co. violated 30 CFR § 75.1704-2(a), which requires that escapeways follow the "safest direct practical route" out of the mine.)

Any person attending this hearing who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR § 2706.1509 (a)(3) and § 2706.160(e).

TIME AND DATE: Immediately following oral argument.

STATUS: Closed [Pursuant to 5 U.S.C. § 552b(c)(10)].

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *Southern Ohio Coal Co.*, Docket No. LAKE 91-650-R, etc. (See Oral Argument Listing)

It was determined by unanimous vote of Commissioners that this meeting be held in closed session.

CONTACT PERSON FOR MORE INFO: Jean Ellen (202) 653-5629/(202) 708-9300 for TDD Relay/1-800-877-8339 for toll free.

Dated: August 20, 1992.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 92-20490 Filed 8-21-92; 3:33 pm]

BILLING CODE 6735-01-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday, August 31, 1992.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: August 21, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-20479 Filed 8-21-92; 3:31 pm]

BILLING CODE 6210-01-M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of August 24, 31, September 7, and 14, 1992.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of August 24

Wednesday, August 26

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of August 31—Tentative

Tuesday, September 1

3:00 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Thursday, September 3

1:00 p.m.
Briefing by EPRI on Status of EPRI Design Requirements Document for Advanced Light Water Reactors (Public Meeting)

Week of September 7—Tentative

Tuesday, September 8

10:00 a.m.
Briefing on Advanced and Evolutionary Reactor Topics: Form and Content for a Design Certification Rule and Follow-up to SECY-90-016 (Public Meeting) (Contact: Dennis Crutchfield, 301/504-1199)

Wednesday, September 9

3:30 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Friday, September 11

8:00 a.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 and 6)
8:30 a.m.
Briefing by Charlie Meinhold on 1990 Recommendations of the International Commission on Radiological Protection (ICRP Publication 60) (Public Meeting)
10:00 a.m.
Periodic Meeting with the Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (Contact: Raymond Fraley, 301/492-8049)

Week of September 14—Tenative

Thursday, September 17

2:00 p.m.
Status Briefing on Shutdown and Low Power Risk Issues (Public Meeting) (Contact: Mark Caruso 301/504-3235)
3:30 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To Verify the Status of Meeting Call (Recording)—(301) 504-1292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 504-1661.

Dated: August 21, 1992.

William M. Hill, Jr.,

Office of the Secretary.

[FR Doc. 92-20482 Filed 8-21-92; 3:32 pm]

BILLING CODE 7590-01-M

federal register

Tuesday
August 25, 1992

Part II

Department of Housing and Urban Development

Office of the Assistant Secretary for Community Planning and Development

Funding Availability for Housing Opportunities for Persons With AIDS; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N-92-3481; FR-3306-N-01]

Notice of Funding Availability for Housing Opportunities for Persons With AIDS

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding availability (NOFA).

SUMMARY: This notice announces the availability of $4,771,000 in funds to be allocated by competition for housing assistance and supportive services under the Housing Opportunities for Persons with AIDS (HOPWA) program. There will be two categories of assistance: (1) Grants to States and localities for projects of national significance; and (2) grants to: (A) States that do not qualify for HOPWA formula allocations; (B) localities outside of eligible metropolitan areas; and (C) localities inside of eligible metropolitan areas that do not have a HUD-approved Comprehensive Housing Affordability Strategy (CHAS). Approximately ten grants will be competitively awarded. The NOFA contains information concerning eligible applicants, the funding available, the application package, and its processing. An Interim Rule containing the requirements and other programmatic information for the HOPWA program was published in the **Federal Register** on July 20, 1992 (57 FR 32106).

DATES: Application packages will be available beginning September 1, 1992 from the HUD field offices listed at the end of this NOFA. Additional information regarding the submission of applications is included in the package.

Applications for HOPWA assistance must be received at HUD's national headquarters by 5:15 p.m. eastern time on October 26, 1992. This application deadline is firm as to date and hour. In the interest of fairness to all competing applicants, the Department will treat as ineligible for consideration any application that is not received on or before the application deadline. Applicants should take this practice into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays or other delivery-related problems.

ADDRESSES: The original application must be sent to the following: James N. Forsberg, Director, Office of Special Needs Assistance Programs, U.S. Department of Housing and Urban Development, room 7262, 451 Seventh Street, SW., Washington, DC 20410–7000. A copy must also be sent to the HUD field office serving the area in which the applicant's project is located. A list of field offices appears at the end of this NOFA. A determination that an application was received on time will be made solely on receipt of the original application at the national office.

FOR FURTHER INFORMATION CONTACT: James N. Forsberg, Director, Office of Special Needs Assistance Programs, Department of Housing and Urban Development, room 7262, 451 Seventh Street, SW., Washington, DC 20410–7000; telephone (202) 708–4300, or for hearing- and speech-impaired persons, (202) 708–2565. (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act Statement

The information collection requirements for the HOPWA program have been approved under the Paperwork Reduction Act of 1980 by the Office of Management and Budget (OMB), and have been assigned OMB control number 2506–0133.

I. Purpose and Substantive Description

(a) Purpose

The HOPWA competitive program will support and encourage the development of approximately five housing assistance and supportive services projects which, due to their unique or innovative nature, are likely to serve as effective models in addressing the housing and related needs of low-income persons living with acquired immunodeficiency syndrome and provide assistance for the development of approximately five additional projects that will address housing and supportive services made of persons with AIDS and related diseases. For the latter projects, assistance may be provided only to: (1) States that do not qualify for HOPWA formula grants; (2) localities outside of eligible metropolitan areas, as defined in 24 CFR 574.3; and (3) localities inside of eligible metropolitan areas that do not have a HUD-approved CHAS.

(b) Authority

The assistance made available under this NOFA is authorized by the AIDS Housing Opportunity Act (Pub. L. 101–625, approved November 28, 1990, 42 U.S.C. 12901–12912), which established the Housing Opportunities for Persons with AIDS (HOPWA) program. The funding was appropriated by the Department's appropriation act for fiscal year 1992 (Pub. L. 102–139, approved October 29, 1991). The Department's Interim Rule for the HOPWA program was published in the **Federal Register** on July 20, 1992 (57 FR 32106).

(c) Allocation Amounts

(1) This NOFA announces the availability of $2,385,000 for grants for projects of national significance.

(2) This NOFA also announces the availability of $2,386,000 for grants to: (i) States that do not qualify for HOPWA formula allocations; (ii) localities outside of eligible metropolitan areas; and (iii) localities inside of eligible metropolitan areas that do not have a HUD-approved CHAS.

(3) HUD expects to award approximately five grants in each of the two categories of assistance. The maximum amount that an applicant may receive is $500,000. HUD reserves the right, however, to make reductions in the amounts requested and, if there are too few applications in one category that rank sufficiently high to be funded, to transfer funds from that category of assistance to the other. Because of the limited number of grants to be awarded, HUD expects an extremely competitive process and strongly suggests that only applications likely to receive a high score under all the selection criteria be submitted.

(d) Eligibility

(1) All States and units of general local government, regardless of whether they qualify for a HOPWA formula allocation, may apply for grants for projects of national significance, as described in 24 CFR 574.250(b)(3).

(2) The only applicants that may apply for grants for other projects are the following:

(A) States that do not qualify for HOPWA formula grants;

(B) localities outside of eligible metropolitan areas; and

(C) localities inside of eligible metropolitan areas that do not have a HUD-approved CHAS. Nonprofit organizations may serve as project sponsors under contract with grantees to operate projects receiving funding under both categories of assistance.

(e) Threshold Review

The selection process for HOPWA includes a preliminary technical threshold review, provided by § 574.250 of the Interim Rule. HUD will conduct its review to determine:

(1) Whether the application is adequate in form, time of submission, and completeness;

(2) Whether the applicant, the population to be served and the proposed project sponsor(s), if any, are eligible;

(3) Whether the proposed activities are eligible for assistance under the program; and

(4) Whether the applicant is currently in compliance with the Federal requirements contained in subpart G (Other Federal Requirements) of the Interim Rule.

(f) Rating Criteria

(1) Applications for grants for projects of national significance that meet the threshold review requirements described in paragraph (e) of this NOFA will be rated based on the following selection criteria:

(i) Applicant Capacity (200 Points)

HUD will award up to 200 points based on the ability of the applicant and, if applicable, any project sponsor(s) to develop and operate the proposed assisted housing and supportive services program. With regard to both the applicant and the project sponsor(s), HUD will consider such factors as the quality of any ongoing programs; past experience in programs serving low-income persons with AIDS and related diseases, including minority persons; management and staffing plans; and other relevant factors.

(ii) Need for the Project in the Area to be Served (200) Points

HUD will award up to 200 points based on the extent of the urgent housing and supportive service needs of eligible persons that are not currently being addressed by available public and private resources within the intended service area, including the relative numbers of AIDS cases and per capita AIDS incidence.

(iii) Appropriateness of Housing and Supportive Services (300 Points)

HUD will award up to 300 points based on the extent to which the proposed activities to be carried out with HOPWA assistance will address the identified needs. In assessing an application under this criterion, HUD will consider the degree to which the applicant demonstrates that proposed activities will provide a continuum of housing and services to meet the changing needs of beneficiaries.

(iv) Extent of Leveraged Public and Private Resources for the Project (100 Points)

HUD will award up to 50 points based on the extent to which the applicant will leverage the amount of assistance requested with funds and other resources from other public or private sources, including the likelihood of the continuation of State and local efforts. HUD also will award up to 50 points based on the extent to which the applicant demonstrates local planning and coordination of housing programs for persons with AIDS.

(v) Innovative Nature of the Proposal (100 Points)

HUD will award up to 100 points based on the extent to which the project involves an exemplary program for, or alternative method of, meeting the needs of low-income persons with AIDS and related diseases, when compared to other applicants; and

(vi) Potential for Replication (100 Points)

HUD will award up to 100 points based on the extent to which the project design, management plan, and service descriptions are appropriate as a model for replication in other similar localities or nationally.

(2) Applications for grants under paragraph (c)(2) of this notice that meet the threshold review requirements described in paragraph (e) of this NOFA will be rated based on the following selection criteria:

(i) Applicant Capacity (200 Points)

HUD will award up to 200 points based on the ability of the applicant and, if applicable, any project sponsor(s) to develop and operate the proposed assisted housing and supportive services program. With regard to both the applicant and the project sponsor(s), HUD will consider such factors as the quality of any ongoing programs; past experience in programs serving low-income persons with AIDS and related diseases, including minority persons; management and staffing plans; and other relevant factors.

(ii) Need for the Project in the Area to be Served (200 Points)

HUD will award up to 200 points based on the extent of the urgent housing and supportive service needs of eligible persons that are not currently being addressed by available public and private resources within the intended service area, including the relative numbers of AIDS cases and per capita AIDS incidence.

(iii) Appropriateness of Housing and Supportive Services (400 Points)

HUD will award up to 400 points based on the extent to which the proposed activities to be carried out with HOPWA assistance will address the identified needs. In assessing an application under this criterion, HUD will consider the degree to which the applicant demonstrates that proposed activities will provide a continuum of housing and services to meet the changing needs of beneficiaries.

(iv) Extent of Leveraged Public and Private Resources for the Project (200 Points)

HUD will award up to 100 points based on the extent to which the applicant will leverage the amount of assistance requested with funds and other resources from other public or private sources, including the likelihood of the continuation of State and local efforts. HUD also will award up to 100 points based on the extent to which the applicant demonstrates local planning and coordination of housing programs for persons with AIDS.

(g) Ratings

Applicants for funds for both categories of assistance will be assigned a rating score and placed in ranked order within their category, based upon the criteria listed in paragraph (f) of this NOFA. The Department will consider the highest rated applicants for final selection in accordance with their ranked order within their category, to the extent that funds are available.

II. Application Submission Requirements

(a) Complete application submission requirements are contained in the application package. Any potential applicants who have questions about the preparation or submission of applications are urged to contact their HUD field office.

(b) Applicants not having a HUD-approved comprehensive housing affordability strategy (CHAS) must submit a CHAS meeting the requirements of 24 CFR part 91, except for applicants eligible under § 574.210(b)(3) of the interim rule.

III. Corrections to Deficient Applications

(a) HUD will notify an applicant, in writing, of any technical deficiencies in the application. The applicant must submit corrections in accordance with the information specified in HUD's letter within 14 calendar days from the date of HUD's letter notifying the applicant of any such deficiency.

(b) Curable technical deficiencies are items that are not necessary for HUD review under the selection criteria (e.g., failure to submit a required certification with the application). Items that would improve the substantive quality of the application may not be submitted after the application due date has expired.

IV. Other Matters

Environmental Impact

A Finding of No Significant Impact with respect to the environment, in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, was made in connection with the interim rule authorizing this program that was published in the **Federal Register** on July 17, 1992 [Docket No. 92-1601]. That Finding of No Significant Impact applies to this NOFA, and it is available for public inspection between 7:30 a.m. to 5:30 p.m. weekdays in the Office of the Rules Docket Clerk at the above address.

Federalism Impact

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this Notice will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. As a result, the Notice is not subject to review under the Order. The Notice announces the availability of funds and invites applications from eligible applicants for the Housing Opportunities for Persons with AIDS program.

Impact on the Family

The General Counsel, as the Designated Official for Executive Order 12606, the Family, has determined that this Notice, to the extent the funds provided under it are directed to families, has the potential for a beneficial impact on family formation, maintenance and general well-being. However, the statutory authority for the program requires that the funds be targeted to individuals with acquired immunodeficiency syndrome and related diseases. Any funding provided to projects which may through other funding sources be incidentally serving families can be expected to enable those families with a participating member who has HIV infection to live in decent, safe, and sanitary housing in connection with the supportive services necessary to live independently in mainstream American society. Since the impact on families, if any, is a beneficial one, no further review is necessary.

Documentation and Public Access Requirements; Applicant/Recipient Disclosures: HUD Reform Act. HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five-year period, beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in its quarterly **Federal Register** notice of all recipients of HUD assistance awarded on a competitive basis. (See 24 CFR 12.14(a) and 12.16(b), and the notice published in the **Federal Register** on January 16, 1992 (57 FR 1942), for further information on these requirements.)

HUD will make available to the public for five years all applicant disclosure reports (HUD Form 2880) submitted in connection with this NOFA. Update reports (also Form 2880) will be made available along with the applicant disclosure reports, but in no case for a period generally less than three years. All reports—both applicant disclosures and updates—will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. (See subpart C, and the notice published in the **Federal Register** on January 16, 1992 (57 FR 1942), for further information on these disclosure requirements.)

Section 103 of HUD Reform Act

HUD's regulation implementing section 103 of the Department of Housing and Urban Development Reform Act of 1989 was published May 13, 1991 (56 FR 22088) and became effective on June 12, 1991. That regulation, codified as 24 CFR part 4, applies to the funding competition announced today. The requirements of the rule continue to apply until the announcement of the selection of successful applicants.

HUD employees involved in the review of applications and in the making of funding decisions are limited by part 4 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted under 24 CFR part 4.

Applicants who have questions should contact the HUD Office of Ethics (202) 708-3815 (TDD/voice). (This is not a toll-free number.) The Office of Ethics can provide information of a general nature to HUD employees, as well. However, a HUD employee who has specific program questions, such as whether particular subject matter can be discussed with persons outside the Department, should contact his or her Regional or Field Office Counsel, or Headquarters for the program to which the question pertains.

Section 112 of HUD Reform Act

Section 112 of the HUD Reform Act amended the Department of Housing and Urban Development Act by adding section 13, which contains two provisions dealing with efforts to influence HUD's decisions with respect to financial assistance. The first imposes disclosure requirements on those who are typically involved in these efforts—those who pay others to influence the award of assistance or the taking of a management action by the Department and those who are paid to provide the influence. The second restricts the payment of fees to those who are paid to influence the award of HUD assistance, if the fees are tied to the number of housing units received or are based on the amount of assistance received, or if they are contingent upon the receipt of assistance.

Section 13 was implemented by final rule codified at 24 CFR part 86 (56 FR 22912, May 17, 1991). If readers are involved in any efforts to influence the Department in these ways, they are urged to read the final rule, particularly the examples contained in Appendix A of the rule.

Any questions about the rule should be directed to Office of Ethics, room 2158, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-3000. Telephone: (202) 708-3815 (TDD/voice). This is not a toll-free number.) Forms necessary for compliance with the rule may be obtained from the local HUD office.

Prohibition Against Lobbying Activities

The use of funds awarded under this NOFA is subject to the disclosure requirements and prohibitions of section 319 of the Department of Interior and Related Agencies Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352)

(The "Byrd Amendment") and the implementing regulations at 24 CFR part 87. These authorities prohibit recipients of federal contracts, grants, or loans from using appropriated funds for lobbying the Executive or Legislative branches of the federal government in connection with a specific contract, grant, or loan. The prohibition also covers the awarding of contracts, grants, cooperative agreements, or loans unless the recipient has made an acceptable certification regarding lobbying. Under 24 CFR part 87, applicants, recipients, and subrecipients of assistance exceeding $100,000 must certify that no federal funds have been or will be spent on lobbying activities in connection with the assistance.

Drug-Free Workplace Certification

In accordance with 24 CFR 24.630, an applicant must submit its Certification for a Drug-Free Workplace (Form HUD-50070).

HUD Field Offices

Telephone numbers for Telecommunications Devices for the Deaf (TDD machines) are listed for field offices; all HUD numbers may be reached via TDD by dialing the Federal Information Relay Service on 1-800-877-TDD or (1-800-877-8339) or (202) 708-9300.

Alabama: Jasper H. Boatright, Beacon Ridge Tower, 600 Beacon Pkwy. West, suite 300, Birmingham, AL 35209-3144; (205) 731-1672; TDD (205) 290-7624

Alaska: Colleen Craig, Federal Bldg., 222 W. 8th Ave., #64, Anchorage, AK 99513-7537; (907) 271-3669; TDD (907) 271-4328

Arizona: Diane Domzalski, 400 N. Fifth St., suite 1600, Arizona Center, Phoenix, AZ 85004; (602) 379-4754; TDD (602) 379-4461

Arkansas: Billy M. Parsley, Lafayette Bldg., 523 Louisiana, suite 200, Little Rock, AR 72201-3707; (501) 324-6375; TDD (501) 324-5931

California: (Southern) Herbert L. Roberts, 1615 W. Olympic Blvd., Los Angeles, CA 90015-3801; (213) 251-7235; TDD (213) 251-7038; (Northern) Gordon H. McKay, 450 Golden Gate Ave., P.O. 36003, San Francisco, CA 94102-3448; (415) 556-5576; TDD (415) 556-8357

Colorado: Barbara Richards, Exec. Tower Bldg., 1405 Curtis St., Denver, CO 80202-2349; (303) 844-3811; TDD (303) 844-6158

Connecticut: Daniel Kolesar, 330 Main St., Hartford, CT 06106-1860; (203) 240-4508; TDD (203) 240-4522

Delaware: John Kane, Liberty Sq. Bldg., 105 S. 7th St., Philadelphia, PA 19106-3392; (215) 597-2665; TDD (215) 597-5564

District of Columbia: James H. McDaniel, 820 First St., NE, Washington, DC 20002; (202) 275-0994; TDD (202) 275-0967

Florida: James N. Nichol, 325 W. Adams St., Jacksonville, FL 32202-4303; (904) 232-3587; TDD (904) 232-1291

Georgia: Charles N. Straub, Russell Fed. Bldg., room 688, 75 Spring St., SW, Atlanta GA 30303-3388; (404) 331-5139; TDD (404) 730-2654

Hawaii: Patti A. Nicholas, 7 Waterfront Plaza, suite 500, 500 Ala Moana Boulevard, Honolulu, HI 96813-4918; (808) 541-1327; TDD (808) 541-1356

Idaho: John G. Bonham, 520 SW 6th Ave., Portland, OR 97204-1596; (503) 326-7018; TDD (503) 326-3656

Illinois: Richard Wilson, 77 W. Jackson Blvd., Chicago, IL 60604-5760; (312) 353-1696; TDD (312) 353-7143

Indiana: Robert F. Poffenberger, 151 N. Delaware St., Indianapolis, IN 46204-2526; (317) 226-5169; TDD (317) 226-6951

Iowa: Gregory A. Bevirt, Braiker/Brandeis Bldg., 210 S. 16th St., Omaha, NE 68102-1622; (402) 221-3703; TDD (402) 492-3102

Kansas: Miguel Madrigal, Gateway Towers 2, 400 State Ave., Kansas City, KS 66101-2406; (913) 236-2184; TDD (913) 236-3972

Kentucky: Ben Cook, P.O. Box 1044, 601 W. Broadway, Louisville, KY 40201-1044; (502) 582-5394; TDD (502) 582-5139

Louisiana: Greg Hamilton, P.O. Box 70288, 1661 Canal St., New Orleans, LA 70112-2887; (504) 589-7212; TDD (504) 589-7237

Maine: David Lafond, Norris Cotton Fed. Bldg., 275 Chestnut St., Manchester, NH 03101-2487; (603) 666-7640; TDD (603) 666-7518

Maryland: Harold Young, Equitable Bldg., 3rd Floor, 10 N. Calvert St., Baltimore, MD 21202-1865; (301) 962-2417; TDD (301) 962-0106

Massachusetts: Frank Del Vecchio, Thomas P. O'Neill, Jr., Fed. Bldg., 10 Causeway St., Boston, MA 02222-1092; (617) 565-5343; TDD (617) 565-5453

Michigan: Richard Paul, Patrick McNamara Bldg., 477 Michigan Ave., Detroit, MI 48226-2592; (313) 226-4343; TDD (313) 226-6898

Minnesota: Shawn Huckleby, 220 2nd St. South, Minneapolis, MN 55401-2195; (612) 370-3019; TDD (612) 370-3186

Mississippi: Jeanie E. Smith, Dr. A. H. McCoy Fed. Bldg., 100 W. Capitol St., room 910, Jackson, MS 39269-1096; (601) 965-4765; TDD (601) 965-4171

Missouri: (Eastern) David H. Long, 1222 Spruce St., St. Louis, MO 63103-2836; (314) 539-6524; TDD (314) 539-6331; (Western) Miguel Madrigal, Gateway Towers 2, 400 State Ave., Kansas City, KS 66101-2406; (913) 236-2184; TDD (913) 236-3972

Montana: Barbara Richards, Exec. Tower Bldg., 1405 Curtis St., Denver, CO 80202-2349; (303) 844-3811; TDD (303) 844-6158

Nebraska: Gregory A. Bevirt, Braiker/Brandeis Bldg., 210 S. 16th St., Omaha, NE 68102-1622; (402) 221-3703; TDD (402) 492-3102

Nevada: (Las Vegas, Clark County) Diane Domzalski, 400 N. 5th St., Suite 1600, 2 Arizona Center, Phoenix, AZ 85004; (602) 379-4754; TDD (602) 379-4461; (Remainder of State) Gordon H. McKay, 450 Golden Gate Ave., P.O. Box 36003, San Francisco, CA 94102-3448; (415) 556-5576; TDD (415) 556-8357

New Hampshire: David Lafond, Norris Cotton Fed. Bldg., 275 Chestnut St., Manchester, NH 03101-2487; (603) 666-7640; TDD (603) 666-7518

New Jersey: Frank Sagarese, Military Park Bldg., 60 Park Pl., Newark, NJ 07102-5504; (201) 877-1776; TDD (201) 645-6649

New Mexico: R.D. Smith, 1600 Throckmorton, P.O. Box 2905, Fort Worth, TX 76113-2905; (817) 885-5483; TDD (817) 885-5447

New York: (Upstate) Michael F. Merrill, Lafayette Ct., 465 Main St., Buffalo, NY 14203-1780; (716) 846-5768; TDD (716) 846-5787; (Downstate) Joan Debelko, 26 Federal Plaza, New York, NY 10278-0068; (212) 264-2885; TDD (212) 264-0927

North Carolina: Charles T. Ferebee, Koger Building, 2306 West Meadowview Road, Greensboro, NC 27407-3707; (919) 547-4005; TDD (919) 547-4055

North Dakota: Barbara Richards, Exec. Tower Bldg., 1405 Curtis St., Denver, CO 80202-2349; (303) 844-3811; TDD (303) 844-6158

Ohio: Jack E. Riordan, 200 North High St., Columbus, OH 43215-2499; (614) 469-6743; TDD (614) 469-6694

Oklahoma: Katie Worsham, Murrah Fed. Bldg., 200 NW. 5th St., Oklahoma City, OK 73102-3202; (405) 231-4973; TDD (405) 231-4181

Oregon: John G. Bonham, 520 SW. 6th Ave., Portland, OR 97204-1596 (503) 326-7018; TDD (503) 326-3656

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Dated: August 17, 1992.

Randall H. Erben,

Acting Assistant Secretary for Community Planning and Development.

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Part III

Environmental Protection Agency

40 CFR 260 et al.

Burning of Hazardous Waste in Boilers and Industrial Furnaces; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, 264, 265, and 266

[EPA/OSW-FR-92-SWH-FRL-4198-5]

Burning of Hazardous Waste in Boilers and Industrial Furnaces

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical clarification amendments and corrections.

SUMMARY: This action makes several technical clarification amendments and corrections to the final rule for boilers and industrial furnaces burning hazardous waste. The final rule was published on February 21, 1991 (56 FR 7134). These revisions provide clarification and correct unintended consequences of the rule.

EFFECTIVE DATE: August 11, 1992.

ADDRESSES: The documents are available for viewing at the RCRA Information Center (docket identification number F-92-BBC3-FFFFF), located at: EPA/RCRA Information Center, room M2427, 401 M Street, SW., Washington, DC 20460.

The RCRA Information Center is open from 9 a.m. to 4 p.m. Monday through Friday, except for federal holidays. The public must make an appointment to review docket materials. Call (202) 260-9327 for appointments. Copies cost $0.15 per page.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at: (800) 424-9346 (toll free) or (703) 920-9810.

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SUPPLEMENTARY INFORMATION:

Preamble Outline

A. Technical Clarification Amendments

1. The Definition of Baseline Hydrocarbon Level for Industrial Furnaces Complying with the Alternative Hydrocarbon Limits is Clarified to Require Consideration of Process Variability.
2. Industrial Furnaces Complying with the Alternative HC Limit May Comply with the Interim HC Limit Using a Conditioned Gas HC Monitoring System if They Demonstrate that a Heated System Is Impracticable.
3. Industrial Furnaces that Cannot Comply with the 20 ppmv HC Limit by Aug. 21, 1992, because of Organic Matter in Raw Materials May Apply for a Case-by-Case Time Extension to Make Physical Changes to the Facility in Order to Comply with that HC Limit.
4. The Metals and Total Chlorine and Chloride Feed Rate Operating Limits for Tier I or Adjusted Tier I Are Based on the Screening Limits, Not the Compliance Test.
5. Adjusted Tier I Feed Rate Screening Limits May Be Used in Dispersion Situations where the Tier I and Tier II Screening Limits Are Precluded.
6. Several Requirements Are Clarified to Account for Facilities that Comply with Adjusted Tier I Limits.
7. BIF Storage Units are Subject to the Air Emissions Standards of subparts AA and BB of parts 264 and 265.
8. The Definitions of Plasma Arc and Infrared Incinerators Are Clarified to Include Only those Devices that Use an Afterburner.
9. Facilities that Comply with the Tier I or Adjusted Tier I Metals and Chlorine Controls and that have Uncontrolled Emissions that Meet the Particulate Matter Standard Need Not Establish a Limit on Production Rate during Interim Status.
10. Halogen Acid Furnaces that Burn Hazardous Waste as an Ingredient Are Subject to the BIF Rule.
11. When Comparing Levels of Nonmetal Constituents in Residue to the Health-Based Limits for the Bevill Exclusion, the Levels Cannot Exceed the Health-Based Limits or the Level of Detection, whichever Is Higher.
12. The Applicability of part 266 Is Clarified.
13. Conforming Revisions Are Made to the Applicability Sections of parts 264 and 265.
14. A Conforming Revision Is Made to the Rulemaking Petitions Provision of part 260.

B. Technical Corrections

C. Immediate Effective Date

A. Technical Clarification Amendments

On February 21, 1991, the Agency published a final rule which regulates the burning of hazardous waste in boilers and industrial furnaces (BIFs). See 56 FR 7134. The rule controls emissions of toxic organic compounds, toxic metals, hydrogen chloride, chlorine gas, and particulate matter from BIFs that burn hazardous waste. In addition, the rules subject owners and operators of BIFs to the general facility and permitting standards applicable to hazardous waste treatment, storage, and disposal facilities.

After publication of the rule, the Agency received many questions and requests for clarification on certain provisions of the rule. In addition, in a number of cases, the Agency was questioned as to whether the rule as promulgated truly reflected the Agency's intent. As a result of these questions and as a result of the Agency's own review, the Agency published a technical amendment to the rule to clarify the operation of the regulation and to correct certain unintended consequences. Those amendments were published at 56 FR 42504 on August 27, 1991. (Note that EPA had previously published several other technical corrections and amendments to the February 21 final rule (56 FR 32688 (July 17, 1991).)

As facilities began to comply with the BIF rules, additional questions have been raised about the way various provisions of the rule are intended to work. Today's technical clarification amendments address those questions.

1. The Definition of Baseline Hydrocarbon Level for Industrial Furnaces Complying With the Alternative Hydrocarbon Limit Is Clarified To Require Consideration of Process Variability

The Cement Kiln Recycling Coalition (CKRC) has expressed concern to the Agency that the alternative hydrocarbon (HC) provision of the rule is problematic for furnaces that feed raw materials containing naturally-occurring organic matter.[1] See § 266.104(f). That provision was intended to allow furnaces that could not comply with the 20 ppmv HC limit because of organic matter in raw materials to comply with an alternative, higher HC limit. EPA's rationale for the 20 ppmb limit was to ensure good hazardous waste combustion conditions and, thus, control of emissions of products of incomplete combustion (PICs). However, because hydrocarbon emissions from organic matter in raw materials are not directly related to fuel-generated hydrocarbons (i.e., from burning normal fuels and hazardous waste fuels), the Agency believed that these hydrocarbon should not be counted toward the 20 ppmv HC limit. See 56 FR 7155-56. To implement the alternative HC limit, the final rule required such furnaces to establish an HC limit that would be applicable when burning hazardous waste as the HC level achieved when not burning hazardous waste and when the furnace is operated to "minimize" HC levels. See § 266.104(f)(1).

CKRC has noted that this provision could be read to limit fuel-generated hydrocarbons to approximately 2 to 5 ppmv—the HC levels that are achieved when cement kilns (and boilers, incinerators, and other industrial furnaces) are operated under conditions to absolutely minimize HC levels. Therefore, although the Agency limits combustion-generated hydrocarbons from other combustion devices to 20 ppmv, the rule could be read to limit fuel-related hydrocarbon levels from cement kilns to 2 to 5 ppmv. In particular, CKRC notes that the rule

[1] See the BIF docket for documentation of meetings and phone conversations and copies of correspondence.

could be interpreted to limit hydrocarbons when burning hazardous waste to the levels achieved when not burning hazardous waste (i.e., baseline conditions) and when kiln is operated to absolutely minimize HC levels and would not allow the facility to account for normal transient combustion conditions that occur because of factors such as mechanically handling coal. These conditions are elements of normal operating variability. Although these transient conditions cause combustion perturbations and momentary increases (i.e., spikes) in HC levels, these combustion-related HC levels do not generally exceed the 20 ppmv hourly rolling average limit that the Agency has established to control PICs.

Nonetheless, the most literal-minded reading of the rule would preclude consideration of these normal combustion perturbations if the rule's requirement that baseline HC levels be established when the kiln is operated to minimize HC levels is read to mean to operate constantly at absolute peak performance.[2] This literal-minded reading would lead to the result—not intended by EPA—that whenever such a normal combustion perturbation would occur (when the kiln is burning hazardous waste) and there is a spike in the HC level that causes the baseline HC level to be exceeded, the kiln would be required to stop burning hazardous waste and not restart the hazardous waste feed until the HC level falls below the baseline limit. Nor did EPA intend that industrial furnaces operate at an absolutely optimized performance in establishing a baseline ignoring normal operating variability (i.e., a performance level analogous to a New Source Performance Standard rather than best available technology). Indeed, the rule refers to establishing a baseline when the industrial furnace "produces normal products under normal operating conditions" (see § 266.104(f)(1)), and the analogous 20 ppmv HC limit itself is an "indicator of good combustion conditions" (see 55 FR 7155), not absolutely optimized combustion.

Although EPA believes these readings take an unduly stringent view of the requirement that HC levels be minimized when establishing a baseline, we nevertheless think it best to clarify the text of the rule. Therefore, EPA is correcting the definition of the baseline HC level provided by § 266.104(f)(1) to make it clear that the measured baseline HC level must be adjusted as appropriate to consider the normal variability of hydrocarbon levels under good combustion operating conditions. Thus, the measured baseline level could be increased by a variability factor that considers normal transient combustion conditions (i.e., provided that the transient conditions do not result in combustion-generated HC that exceed the 20 ppmv limit provided by § 266.104(c)). Accordingly, today's clarification amends the definition of the baseline HC level in § 266.104(f)(1) to read as follows: "The baseline HC level is defined as the average over all valid test runs of the highest hourly rolling average value for each run, adjusted as appropriate to consider the variability of hydrocarbon levels under good combustion operating conditions."

This HC variability factor would be determined on a case-by-case basis by the Director. As guidance in determining what variability factor to apply, EPA believes that a factor of 10 ppmv would be appropriate in most situations.[3] As indicated previously, the Agency believes that combustion-generated HC levels from cement kilns (and other furnaces eligible for the alternative HC limit) should be limited to 20 ppmv to ensure good combustion conditions. This is the same HC limit that applies to boilers, other furnaces, and incinerators, and provides a "level playing field" with respect to control of combustion-generated hydrocarbons. Thus, we recommend that the alternative HC limit be established as 20 ppmv plus the raw material-generated HC level. We do not believe that it is feasible, however, to measure only raw material-generated hydrocarbons; the HC monitor in the stack measures both hazardous waste combustion-generated and raw material-generated hydrocarbons. Therefore, to estimate the level of raw material-generated hydrocarbons, it is conservative and reasonable to assume that 10 ppmv [4] of the HC measured under baseline conditions (when the kiln must be operated to minimize combustion-generated hydrocarbons) is attributable to hazardous waste combustion. (Note that when the kiln is operated to absolutely minimize hazardous waste combustion-generated hydrocarbons, HC levels should be in the range of 2 to 5 ppmv. Thus, the recommended assumption that combustion-generated hydrocarbons are 10 ppmv during baseline testing is conservative.[5] Under this approach, raw material-generated hydrocarbons are estimated to be the measured HC level during baseline testing minus 10 ppmv. The 20 ppmv combustion-generated HC allowance would then be added to the estimated raw material-generated hydrocarbons. The net effect would be simply to add 10 ppmv to the measured baseline HC level.

As discussed above, the rational for adding a variability factor to the measured baseline HC level assumes that the baseline level is determined when the device is operated under conditions that generally minimize combustion-generated hydrocarbon.[6] Therefore, combustion-generated hydrocarbon spikes causing a significant increase in the hourly rolling average HC level should not be allowed during baseline testing. To ensure that substantial variability is not already included in the baseline HC level, the hourly rolling average hydrocarbon level should not vary during baseline testing by more than 5 ppmv when measured HC levels are in the range of 10–30 ppmv. When measured HC levels exceed 30 ppmv, then a higher allowable range of HC levels (i.e., the difference

[2] Even if the rule were interpreted to allow normal combustion perturbations (i.e., perturbations that do not result in combustion-generated hydrocarbons exceeding 20 ppmv on an hourly rolling average, and thus, are within the Agency's definition of good combustion conditions) during baseline testing, establishing a baseline that includes such normal perturbations would be problematic. This is because the owner or operator cannot ensure that the perturbations that occur during the baseline testing are representative (i.e., in frequency, magnitude, and duration) of normal perturbations. The occurrence of normal perturbations cannot always be predicted, and it would be difficult for the owner or operator to demonstrate that perturbations that could be artificially induced during baseline testing are representative of normal perturbations.

[3] We note that, if a variability of 10 ppmv is used to adjust he measured baseline HC level, facilities with measured HC levels of 11 ppmv or greater would be eligible for the alternative HC limit. This is because the baseline HC level, when adjusted for the 10 ppmv variability factor, would be 21 ppmv or more and facilities with baseline HC levels exceeding 20 ppmv are eligible for the alternative HC limit.

[4] Note that the assumption that 10 ppmv of HC during baseline testing is attributable to hazardous waste combustion is not the basis for the recommended 10 ppmv variability factor. As discussed in the text, however, this assumption leads to the Agency's conclusion that a 10 ppmv variability factor is appropriate.

[5] The assumption that combustion-generated HC is 10 ppmv during baseline testing is conservative because if, for example, we assumed that combustion-generated HC is 5 ppmv, the variability factor would be 15 ppmv, not 10 ppmv. This is because, the lower that the combustion-generated HC is assumed to be, the higher the raw material-generated HC is estimated to be, and the 20 ppmv allowance for combustion-generated HC is added to the estimated raw material-generated HC.

[6] Although it is not practicable for an industrial furnace to operate continuously under conditions that minimize combustion-generated HC as discussed previously in the text, it is reasonable and necessary to require the facility to operate during baseline testing under conditions that generally minimize combustion-generated HC. This is because, otherwise, a variability factor would be added to a baseline HC level that may already include substantial variability.

between the highest and lowest hourly rolling average level) during baseline testing may be appropriate given that the absolute HC levels are higher and even minor perturbations could cause significant changes in HC levels.[7]

EPA is interested in obtaining further information on whether this recommended approach is reasonable to establish an alternative HC limit for devices that cannot meet the 20 ppmv HC limit because of organic matter in raw materials. EPA therefore invites all interested persons to submit any relevant information on this issue.

2. Industrial Furnaces Complying With the Alternative HC Limit May Comply With the Interim HC Limit Using a Conditioned Gas HC Monitoring System if They Demonstrate That a Heated System Is Impracticable

Section 266.103(c)(5) of the rule allows owners and operators of BIFs, other than those that obtain a time extension, to certify compliance with the 20 ppmv HC limit using a conditioned gas (i.e., cold) HC monitoring system rather than a heated monitoring system. Although the Agency prefers the heated system because a cold system may remove some hydrocarbons during gas conditioning (e.g., chilling the gas sample line to condense water vapor can also remove hydrocarbons), the Agency recognized that heated systems are not in widespread use on BIFs and modifications to the monitoring systems may be necessary to address operation and maintenance problems. See 56 FR 7162 (February, 21, 1991). Consequently, the Agency reasoned that facilities that comply with the HC limit on Aug. 21, 1992, should be allowed to use a cold system. On the other hand, he Agency reasoned that those owners and operators who obtain a time extension should be required to certify compliance with a hot system given that the time extension should provide enough time to resolve operation and maintenance problems. (Note that facilities that elect to certify compliance with a cold system on Aug. 21, 1992, must use a hot system when they recertify compliance under interim status or obtain a RCRA operating permit. See § 266.103(c)(5).

The Agency did not anticipated the consequences that this requirement would have on cement kilns complying with the alternative hydrocarbon provision of §§ 266.104(f) and 266.103(c)(7)(ii)(B). Under those requirements, cement kilns must, prior to August 21, 1992, submit a complete Part B permit application that includes documentation of the baseline HC level, and obtain a time extension from the Director. Until the operating permit is issued, the facility must comply with an interim HC (and CO) limit effective no later than August 21, 1992, that is established as a condition of the time extension.

Consequently, although cement kilns complying with the alternative hydrocarbon provision must obtain a time extension, they must monitor hydrocarbons prior to August 21, 1992, in order to establish the baseline HC level, and must monitor hydrocarbons continuously beginning August 21, 1992. Thus, § 266.103(c)(5) has the unintended consequence of requiring such facilities to use a hot HC monitoring system on (and before) August 21, 1992.

As discussed above, the Agency has already determined that this is infeasible (and therefore provided a conditioned (i.e., cold) monitoring option). Therefore, to give such facilities the time they may need to resolve operating and maintenance problems with hot monitoring systems, today's technical correction revises § 266.103(c)(5) to enable the Director to approve on a case-by-case basis the use of a cold system for establishing the baseline HC level and complying with the alternative, interim HC limit. This correction is a logical and necessary adjunct to the existing regulation that allows the alternative use of cold HC monitoring systems. The Director's approval will be based on a demonstration by the facility that it has made a good faith effort to install and operate a heated system but that it has determined that continuous operation is not practicable at this time. The Agency does not believe that this demonstration will be a burden on owners and operators because they have known since February 21, 1991, that a hot monitoring system was required by the rule and should have been attempting to operate continuously such systems for some time.

In considering a request to use a conditioned gas monitor in lieu of a hot monitor, the Director may impose additional requirements on the owner and operator of the facility to ensure that a hot monitoring system is installed as soon as practicable. See § 266.103(c)(7)(ii)(A). For example, the Director may require the owner or operator to operate a hot monitoring system to the extent practicable concurrently with a conditioned gas monitoring system in order to meet specified milestones in activities designed to resolve operational problems with a heated HC monitoring system, and to report periodically on progress toward achieving sustained operation of the hot monitoring system.

This amendment does not extend the deadline for certification of compliance. Owners and operators requesting to comply with the alternative hydrocarbon limit are required to submit their request along with accompanying supporting materials in time to allow the Director to grant or deny the request by August 21, 1992.

3. Industrial Furnaces That Cannot Comply With the 20 PPMY HC Limit by August 21, 1992, Because of Organic Matter in Raw Materials May Apply for a Case-by-Case Time Extension To Make Physical Changes to the Facility in Order to Comply With That HC Limit

The Agency is clarifying the rule to make it clear that industrial furnaces that cannot comply with the 20 ppmv HC limit for reasons beyond the owner's or operator's control may request a time extension to certify compliance with the HC limit. The final rule allows facilities that elected to comply with the alternative hydrocarbon provisions of § 266.104(f) to obtain a time extension under § 266.103(c)(7)(ii)(B). However, the Agency inadvertently did not make it clear that owners and operators that elected to make physical changes to the facility to enable them to comply with the 20 ppmv HC limit (i.e., the usual HC limit, rather than an alternative limit established on a case-by-case basis) but who cannot do so by August 21, 1992, for reasons beyond their control are also eligible to request a time extension under § 266.103(c)(7)(ii).

EPA meant for § 266.103(c)(7)(ii) (B) to apply only to facilities that comply with the alternative HC limit, and believes that this intent is fairly clear in the existing regulatory language since the provision (§ 266.103(c)(7)(ii)(B)(2)) references the procedure for establishing CO and HC baseline levels (§ 266.104(f)(1)) applicable only to persons complying with the alternative HC limit. Conversely, the provisions make little sense for persons who intend to comply with the limit of 20 ppmv because the requirements in § 266.103(c)(7)(ii)(B) are related only to the alternative HC limit.

Accordingly, today's amendment revises § 266.103(c)(7)(ii)(B) to clarify that paragraph applies only to facilities that comply with the alternative HC limit. Thus, the general time extension provision of § 266.103(c)(7)(ii) applies to all other situations, including industrial furnaces that need time to modify the

[7] Baseline testing should consist of a minimum of three test runs, with each run having a minimum duration of three hours.

facility to comply with the 20 ppmv HC limit.

Industrial furnaces such as cement kilns may elect to make physical modifications to the facility to enable them to certify compliance with the 20 ppmv HC limit rather than to comply with the alternative HC provisions of § 266.104(f). If those modifications cannot be completed in time to enable the facility to certify compliance by August 21, 1992, for reasons beyond the facility's control, the owner or operator may request a time extension.

If a time extension is granted, the Director will use the authority of § 266.103(c)(7)(ii) to establish operating conditions as necessary to reasonably ensure that emissions of toxic organic compounds do not pose a threat to human health and the environment. Operating conditions that may be applied may include limits on the type, quantity, and method of firing hazardous waste, and limits on combustion parameters such as oxygen, carbon monoxide, and hydrocarbons.

Examples of physical changes that may be made to the facility in order to meet the 20 ppmv HC limit are: (1) Installation of a secondary combustion chamber to destroy organic compounds in the kiln off-gas; or (2) installation of a roaster to volatilize organic compounds from the raw material before feeding it to the kiln where hazardous waste is burned. These changes may enable the owner or operator to demonstrate that stack gas concentrations do not exceed the 20 ppmv limit. At this time, the Agency has not evaluated the practicability of installing a secondary combustion chamber or roaster to reduce HC emissions. The Agency is simply identifying these as conceivable changes that may enable a facility to meet the 20 ppmv HC limit.

4. The Metals and Total Chlorine and Chloride Feed Rate Operating Limits for Tier I or Adjusted Tier I Are Based on the Screening Limits, Not the Compliance Test

The final rule requires facilities that comply with the Tier I or Adjusted Tier I feed rate screening limits for metals and total chlorine and chloride to establish feed rate limits based on the feed rates used during the compliance test, and to establish feed rate limits on both pumpable and total hazardous waste feeds. In addition, the final rule requires the owner or operator to conduct a compliance test to document compliance with the particulate matter (PM) limit even though a facility may comply with the Tier I or Adjusted Tier I feed rate screening limits for metals and total chlorine and chloride.

As discussed in the preamble to the final rule (56 FR 7175 (February 21, 1991)), the Tier I or Adjusted Tier I feed rate screening limits are protective of human health and the environment because the limits are back-calculated from acceptable ambient levels using conservative dispersion scenarios, and because the limits are based on an assumption that all metals and chlorine feed to the BIF are emitted (i.e., metals and chlorine do not partition to ash or product and are not removed by an air pollution control system). Because of this, the Agency did not intend for facilities complying with Tier I or Adjusted Tier I to establish feed rate limits on metals or chlorine during a compliance test; rather, the feed rate limits on metals and chlorine are established by the reference tables in appendices I and II of part 266. Further, given that the Tier I or Adjusted Tier I compliance approaches assume that all metals or chlorine fed to the BIF are emitted, it is not necessary to establish a separate feed rate limit for these parameters on pumpable or total hazardous waste. The feed rate limits under Tier I or Adjusted Tier I are based on the total feed rate in total feed streams, and are limited to the levels established in appendices I and II of part 266. (Note, however, that in order to ensure and document compliance with the feed rate screening limits, the facility must nonetheless know the feed rate of metal or chlorine in each feed stream at all times.)

In addition, the Agency considered whether facilities complying with the Tier I or Adjusted Tier I limits for metals and total chlorine and chloride during the compliance test should be required to feed metals and chlorine at the maximum rate during the PM emissions test to ensure maximum PM emissions. As discussed in the preamble to the final rule (56 FR 7144), the Agency is not regulating PM emissions under RCRA per se, but rather as a secondary control on emissions of metals and organics that could be adsorbed on the PM. Given that the Tier I or Adjusted Tier I metals and chlorine feed rate screening limits ensure protection of human health and the environment, the Agency does not believe that it is necessary to spike metals and chlorine at the screening feed rate limits during the PM compliance test.

To make sure that these requirements are fully understood the Agency is amending §§ 266.103(c)(1), 266.103(c)(1)(ii)(A), and 266.103(c)(1)(iii) to clarify that the Tier I or Adjusted Tier I feed rate limits are based on the feed rate screening limits specified under §§ 266.106 (b) or (e) (for metals) and 266.107 (b)(1) or (e) (for chlorine) and are not based on the actual feed rates demonstrated during the compliance test. Further, the Agency is clarifying §§ 266.103(b)(3)(ii)(B) and 266.103(c)(1)(ii)(C) by deleting the requirements for metals feed rate limits in total hazardous waste feed and in total pumpable hazardous waste feed when the BIF complies with the Tier I or Adjusted Tier I metals feed rate screening limits.

5. Adjusted Tier I Feed Rate Screening Limits May Be Used in Dispersion Situations Where the Tier I and Tier II Screening Limits Are Precluded

Sections 266.106(b)(7) and 266.107(b)(3) of the rule preclude the use of the Tier I and Tier II Screening Limits for facilities located in areas where the dispersion characteristics would be worse than were used to calculate the screening limits. Facilities in such situations must conduct dispersion modeling to ensure that the ambient concentrations will not exceed allowable levels. In drafting the final rule, the Agency inadvertently precluded the use of Adjusted Tier I when dispersion characteristics precluded the use of the Tier I and Tier II Screening Limits. Therefore, the Agency is clarifying those paragraphs to allow facilities to apply either the Tier III or Adjusted Tier I feed rate screening limits to control metals and $HC1/Cl_2$ emissions.

As explained in the final rule, the Agency established the Tier I and Tier II Screening Limits using dispersion modeling; such modeling included a number of conservative assumptions. Despite the conservatism, several situations still existed whereby the Tier I or Tier II limits could result in exposure levels that exceed those established as acceptable in the rule. These specific situations are listed in § 266.106(b)(7). In these situations, facilities are required to conduct dispersion modeling to ensure that metals (or $HC1/Cl_2$) concentrations will not exceed allowable levels. Such dispersion modeling is required under both Tier III and Adjusted Tier I standards. However, the Agency inadvertently specified that facilities must comply with Tier III limits when the facility is located in one of the specified nonconservative dispersion situations. Because the same dispersion modeling is required for the Adjusted Tier I standards as for the Tier III standards, this correction makes it clear that facilities may comply with either Adjusted Tier I or Tier III in these situations.

6. Several Requirements Are Clarified to Account for Facilities That Comply With Adjusted Tier I Limits

When prescribing requirements for certification of precompliance in § 266.103(b), the Agency did not make it clear that the requirements in paragraphs (b)(2) (ii) and (iii) that apply to facilities that choose to comply with the Tier I controls also apply to facilities that elect to comply with the Adjusted Tier I controls for metals or total chlorine and chloride, although EPA believes this result is implicit since there is no logical reason for the requirements to apply in one case but not the other. Accordingly, today's amendments simply clarifies that these provisions also are applicable to facilities that comply with Adjusted Tier I controls.

Similarly, the Agency inadvertently did not require in § 266.106(d) that facilities complying with the Adjusted Tier I controls on metals emissions to also comply with most of the requirements applicable to facilities that comply with Tier III controls, although the February 21, 1991, preamble clearly indicates that these requirements do apply. See 56 FR 7175. Accordingly, the Agency is also clarifying paragraph (d) to add an introductory sentence and revise paragraphs (d) (1) and (5) to apply the appropriate requirements to facilities complying with the Adjusted Tier I controls.

7. BIF Storage Units Are Subject to the Air Emissions Standards of Subparts AA and BB of Parts 264 and 265

The final rule subjects storage units for hazardous waste burned in BIFs to the requirements of subparts A through L of parts 264 and 265. See § 266.101(c)(1). The Agency inadvertently omitted reference to subparts AA and BB of parts 264 and 265 that establish air emission standards for process vents and equipment leaks, respectively. Given that these air emissions standards apply to other hazardous waste storage units and are necessary to protect human health and the environment, they apply to storage units for hazardous waste burned in BIFs as well.

To implement this amendment, we are revising § 266.101(c)(1) to require compliance with the requirements of parts 264 and 265 that are applicable to storage units. This approach is preferable to adding a reference specifically to subparts AA and BB because the Agency may add over time other subparts that are applicable to storage units.

In addition, we are amending § 266.101(c)(2) for the same reasons. That paragraph conditionally exempts storage units for exempt small quantity burners from applicable regulations under parts 264, 265, and 270.

8. The Definitions of Plasma Arc and Infrared Incinerators Are Clarified To Include Only Those Devices That Use an Afterburner

In the February 21, 1991 final BIF rule, EPA modified the definition of incinerator in § 260.10 to explicitly include plasma arc and infrared devices as incinerators. See 56 FR 7206. The Agency added the devices to the incinerator definition to make it clear that they were to be regulated as incinerators because: "(1) Although these devices use nonflame sources of thermal energy to treat waste in the primary chamber, they *invariably employ controlled flame afterburners* to combust hydrocarbons * * *" (emphasis added); and "(2) the incinerator standards are workable and protective for these units."

Since promulgation of the final rule, a number of questions have been raised as to whether the Agency intended to classify as incinerators those plasma arc units that treat the off-gas by methods (e.g., condensation, catalytic converters) other than by combustion in a controlled flame afterburner.[8] As indicated above, the Agency made this modification based on the (incorrect) understanding that these units invariably use controlled flame combustion in the afterburner. Given that there are plasma arc or infrared units that do not use controlled flame combustion in an afterburner or other device—that is, they do not meet the definition of incinerator (i.e., before the Agency amended the definition to include plasma arc and infrared units)—and the incinerator regulations are not appropriate for devices not employing combustion, the Agency is today clarifying the definitions of these units to specifically refer to the use of such an afterburner (as stated in the February 21, 1991, preamble).

Plasma arc and infrared devices that are not incinerators because they do not use controlled flame combustion in an afterburner are subject to regulation under subpart P, part 265 (for units in interim status) and subpart X, part 264 (for units operating under a RCRA permit).

Finally, we note that the revisions to these definitions (being non-HSWA) do not take effect in an authorized state until the state becomes authorized for the rule change.

9. Facilities That Comply With the Tier I or Adjusted Tier I Metals and Chlorine Controls and That Have Uncontrolled Emissions That Meet the Particulate Matter Standard Need Not Establish a Limit on Production Rate During Interim Status

Sections 266.103(b)(3)(v) and 266.103(c)(vi) of the rule require BIFs to establish an operating limit during interim status on maximum production rate when producing normal product. The Agency required a limit on maximum production rate as a surrogate for gas flow rate through the air pollution control system (APCS) to ensure that the collection efficiency of the system would not be compromised at higher gas flow rates—and higher production rates—than occurred during the compliance test. In drafting the final rule, the Agency inadvertently required that a limit on maximum production rate be established during interim status in a situation where a limit is not needed—when an APCS is not needed to comply with the emissions standards for metals, HCl, Cl_2, or particulate matter (PM).

Consequently, EPA is correcting the rule to indicate that the requirement to establish a maximum production rate during interim status is not necessary when: (1) The BIF complies with Tier I or Adjusted Tier I feed rate limits for all metals and total chlorine and chloride (which are conservatively based on a reasonable, worst-case dispersion scenario and assume that all metals and chlorine fed to the BIF are emitted (i.e., no partitioning to bottom ash or product and no removal by an APCS)); and (2) uncontrolled stack emissions comply with the PM standard (i.e., when there is no APCS or when emissions at the inlet to an APCS meet the PM standard).

10. Halogen Acid Furnaces That Burn Hazardous Waste as an Ingredient Are Subject to the BIF Rule

In the BIF rule published on Feb. 21, 1991, the Agency amended § 261.2(d) to list as inherently waste-like any secondary material that is identified or listed as a hazardous waste and that is fed to a halogen acid furnace (HAF). See 56 FR 7141 for the reasons for this rule. By doing this, the Agency made clear that burning of secondary materials in HAFs that exhibit a characteristic or are specifically listed would subject those

[8] See the memorandum from Sylvia Lowrance, Director, Office of Solid Waste, EPA, to Allyn M. Davis, Director, Region VI Hazardous Waste Management Division dated September 30, 1991, stating that the BIF rule unintentionally includes as incinerators plasma arc and infrared units not equipped with an afterburner, and that the Agency intends to issue a technical correction to the incinerator definition to address the error.

units to the BIF regulations. While the Agency revised § 261.2(d) by adding paragraph (d)(2), the Agency inadvertently did not make a conforming change to § 261.2(e)(2)(iv) that identifies materials that are solid wastes, even if the recycling involves use, reuse, or return to the original process. Accordingly, the Agency is today revising § 261.2(e)(2)(iv) to include a reference to paragraph (d)(2) to make it clear that inherently waste-like materials burned in a HAF are solid (and hazardous) wastes even if such burning is recycling by use, reuse, or return to the original process.

11. When Comparing Levels of Nonmetal Constituents in Residue to the Health-Based Limits for the Bevill Exclusion, the Levels Cannot Exceed the Health-Based Limits or the Level of Detection, Whichever Is Higher

Section 266.112 of the BIF rule prescribes requirements for determining whether residues from certain devices retain the Bevill exclusion. See 56 FR 7196–7200 (Feb. 21, 1991). Paragraph (b)(2)(i) of that section provides for a comparison of nonmetal constituents in the waste-derived residue to health-based limits established in the rule (see appendix VII, part 266) in determining whether the residue would retain the Bevill exclusion. This paragraph also indicates that if a health-based limit for a constituent was not included in appendix VII, then a default limit of 0.002 micrograms per kilogram or the level of detection, whichever is higher must be used. A number of questions have been raised to the Agency as to how an owner or operator is to make this determination if a health-based level is identified in appendix VII but the analytical detection level for that constituent(s) exceeds the health-based level.

As indicated above, the Agency addressed this issue for those constituents for which a health-based limit was not identified in appendix VII, part 266 (i.e., those constituents subject to the default limit of 0.002 micrograms per kilogram). In these circumstances, the owner or operator had to meet either a level of 0.002 micrograms per kilogram or the level of detection, whichever is higher. The Agency took this approach because of concern that the level of analytical detection for nonmetal constituents in kiln dust may be higher than the default limit of 0.002 micrograms per kilogram. In these situations, the owner or operator could not document compliance with the 0.002 micrograms per kilogram limit even when using the SW–846 analytical procedure providing the lowest level of detection.

For the same reason, the Agency also intended to cap the health-based limit by the level of detection for a constituent(s) for which a health-based limit (i.e., other than the default limit) is established in appendix VII, part 266. However, the rule inadvertently does not include that language. To clarify this provision, we are today modifying the rule to require that, for purposes of complying with paragraph (b)(2)(i), the concentration of each nonmetal constituent in the waste-derived residue cannot exceed the health-based limit established in appendix VII, part 266, or the level of detection, whichever is higher.

12. The Applicability of Part 266 Is Clarified

In the Technical Amendments to the final BIF rule published at 56 FR 42513 (Aug. 27, 1991), EPA amended § 266.100 (Applicability) to add paragraph (f) that exempted precious metal recovery furnaces from the BIF rule. The Agency also made a conforming revision to paragraph (a) of that section to add "and (f)" in the first sentence. The Agency subsequently made other changes to § 266.100 and published those changes at 56 FR 43877 (Sept. 5, 1991). In the September 5 notice, the Agency inadvertently neglected to include the earlier amendment by which "and (f)" was added to the first sentence of § 266.100. To correct this omission, we are reissuing in today's notice the amendment to paragraph (a) made on August 27.

13. Conforming Revisions are Made to the Applicability Sections of Parts 264 and 265

The BIF rule, which is codified as subpart H, part 266, replaced regulations for burning hazardous waste for energy recovery that were codified in subpart D, part 266. When the BIF rule was promulgated, the Agency inadvertently did not make conforming revisions to the applicability sections of parts 264 and 265. Consequently, the Agency is today revising §§ 264.1(g)(2) and 265.1(c)(6) (which exempt facilities managing recyclable materials except to the extent that requirements in those parts are referred to in subparts to part 266) to delete reference to (now reserved) subpart D, part 266, and to reference subpart H, part 266.

14. A Conforming Revision Is Made to the Rulemaking Petitions Provision of Part 260

When part 266 was established, the Agency inadvertently did not make a conforming revision to § 260.20(a) to allow rulemaking petitions to be submitted to the Administrator to modify or revoke any provisions of part 266. Section 260.20(a) already allows rulemaking petitions to parts 260 through 265 and 268. Accordingly, § 260.20(a) is amended today to also refer to part 266.

B. Technical Corrections

On July 17, 1992, and August 27, 1991, EPA published several technical corrections and amendments to the February 21 final rule (see 56 FR 32688 and 42504). Today's notice corrects several errors published in those notices.

C. Immediate Effective Date

EPA has determined to make today's action effective immediately. The Agency believes that the corrections being made in this notice are either interpretations of existing regulations which do not require prior notice and opportunity for comment (corrections 1, 3, and 11), or are technical corrections of obvious errors in the rule (for example, corrections of regulatory language that is inconsistent with the preamble or with otherwise clearly indicated Agency intent) for which comment is unnecessary (within the meaning of 5 U.S.C. 553(b)(3)(B)) (the remaining corrections).

List of Subjects

40 CFR Part 260

Administrative practice and procedure, Confidential business information, Hazardous waste.

40 CFR Part 261

Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 264

Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 266

Energy, Hazardous waste, Petroleum, Recycling, Reporting and recordkeeping requirements.

Dated: August 11, 1992.

Don R. Clay,

Assistant Administrator for Solid Waste and Emergency Response.

For the reasons set out in the preamble, 40 CFR parts 260, 261, 264, 265, and 266 are amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

I. In part 260:

1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

2. In § 260.10, the definitions for "Infrared incinerator" and "Plasma arc incinerator" are revised to read as follows:

§ 260.10 Definitions.

* * * * *

Infrared incinerator means any enclosed device that uses electric powered resistance heaters as a source of radiant heat followed by an afterburner using controlled flame combustion and which is not listed as an industrial furnace.

* * * * *

Plasma arc incinerator means any enclosed device using a high intensity electrical discharge or arc as a source of heat followed by an afterburner using controlled flame combustion and which is not listed as an industrial furnace.

* * * * *

3. In § 260.20, the first sentence of paragraph (a) is revised to read as follows:

§ 260.20 General.

(a) Any person may petition the Administrator to modify or revoke any provision in parts 260 through 266 and 268 of this chapter. * * *

* * * * *

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

II. In part 261:

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

2. Section 261.2 is amended by revising paragraph (e)(2)(iv) to read as follows:

§ 261.2 Definition of solid waste.

* * * * *

(e) * * *

(2) * * *

(iv) Materials listed in paragraphs (d)(1) and (d)(2) of this section.

* * * * *

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

III. In part 264:

1. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, and 6925.

2. In § 264.1, paragraph (g)(2) is revised to read as follows:

§ 264.1 Purpose, scope, and applicability.

* * * * *

(g) * * *

(1) * * *

(2) The owner or operator of a facility managing recyclable materials described in § 261.6(a) (2) and (3) of this chapter (except to the extent that requirements of this part are referred to in subparts C, F, G, or H of part 266 of this chapter).

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

IV. In part 265:

1. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6935.

2. In § 265.1, paragraph (c)(6) is revised to read as follows:

§ 265.1 Purpose, scope, and applicability.

* * * * *

(c) * * *

(6) The owner and operator of a facility managing recyclable materials described in § 261.6(a) (2) and (3) of this chapter (except to the extent that requirements of this part are referred to in subparts C, F, G, or H of part 266 of this chapter).

* * * * *

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

V. In part 266:

1. The authority citation for part 266 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004, and 3014 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6924, and 6934).

2. In § 266.100, paragraph (a) is amended by revising the first sentence to read as follows, and paragraph (f) introductory text is amended by revising, "§ 261.111" to read "§ 266.111".

§ 266.100 Applicability.

(a) The regulations of this subpart apply to hazardous waste burned or processed in a boiler or industrial furnace (as defined in § 260.10 of this chapter) irrespective of the purpose of burning or processing, except as provided by paragraphs (b), (c), (d), and (f) of this section. * * *

* * * * *

3. In § 266.101, the first sentence of paragraph (c)(1), and paragraph (c)(2) are revised to read as follows:

§ 266.101 Management prior to burning.

* * * * *

(c) *Storage Facilities.* (1) Owners and operators of facilities that store hazardous waste that is burned in a boiler or industrial furnace are subject to the applicable provisions of parts 264, 265, and 270 of this chapter, except as provided by paragraph (c)(2) of this section. * * *

(2) Owners and operators of facilities that burn, in an onsite boiler or industrial furnace exempt from regulation under the small quantity burner provisions of § 266.108, hazardous waste that they generate are exempt from the regulations of parts 264, 265, and 270 of this chapter applicable to storage units for those storage units that store mixtures of hazardous waste and the primary fuel to the boiler or industrial furnace in tanks that feed the fuel mixture directly to the burner. Storage of hazardous waste prior to mixing with the primary fuel is subject to regulation as prescribed in paragraph (c)(1) of this section.

4. Section 266.103 is amended by revising paragraphs (b)(2)(ii) introductory text and (iii), (b)(3)(ii)(B), (b)(3)(v), (c)(1) introductory text, (c)(1)(ii) (A) and (C), (c)(1)(iii), (c)(1)(vi), (c)(5), and (c)(7)(ii)(B) to read as follows:

§ 266.103 Interim status standards for burners.

(b) * * *

(2) * * *

(ii) Except for facilities complying with the Tier I or Adjusted Tier I feed rate screening limits for metals or total chlorine and chloride provided by §§ 266.106 (b) or (e) and 266.107 (b)(1) or (e), respectively, the estimated uncontrolled (at the inlet to the air pollution control system) emissions of particulate matter, each metal controlled by § 266.106, and hydrogen chloride and

chlorine, and the following information to support such determinations:

* * * * *

(iii) For facilities complying with the Tier I or Adjusted Tier I feed rate screening limits for metals or total chlorine and chloride provided by §§ 266.106 (b) or (e) and 266.107 (b)(1) or (e), the feed rate (lb/hr) of total chloride and chlorine, antimony, arsenic, barium, beryllium, cadmium, chromium, lead, mercury, silver, and thallium in each feed stream (hazardous waste, other fuels, industrial furnace feedstocks).

* * * * *

(3) * * *

(ii) * * *

(B) Total hazardous waste feed, unless complying with the Tier I or Adjusted Tier I metals feed rate screening limits under § 266.106 (b) or (e); and

* * * * *

(v) Maximum production rate of the device in appropriate units when producing normal product, unless complying with the Tier I or Adjusted Tier I feed rate screening limits for chlorine under § 266.107 (b)(1) or (e) and for all metals under § 266.106 (b) or (e), and the uncontrolled particulate emissions do not exceed the standard under § 266.105.

* * * * *

(c) * * *

(1) *Limits on operating conditions.* The owner or operator shall establish limits on the following parameters based on operations during the compliance test (under procedures prescribed in paragraph (c)(4)(iv) of this section) or as otherwise specified and include these limits with the certification of compliance. The boiler or industrial furnace must be operated in accordance with these operating limits and the applicable emissions standards of §§ 266.104 (b) through (e), 266.105, 266.106, 266.107, and 266.103(a)(5)(I)(D) at all times when there is hazardous waste in the unit.

* * * * *

(ii) * * *

(A) Total feedstreams, except that:

(*1*) Facilities that comply with Tier I or Adjusted Tier I metals feed rate screening limits may set their operating limits at the metals feed rate screening limits determined under § 266.106 (b) or (e); and

(*2*) Industrial furnaces that must comply with the alternative metals implementation approach under paragraph (c)(3)(ii) of this section must specify limits on the concentration of each metal in the collected particulate matter in lieu of feed rate limits for total feedstreams;

(B) * * *

(C) Total pumpable hazardous waste feed (unless complying with the Tier I or Adjusted Tier I metals feed rate screening limits under § 266.106 (b) or (e);

(iii) Total feed rate of chlorine and chloride in total feed streams, except that facilities that comply with Tier I or Adjusted Tier I feed rate screening limits may set their operating limits at the total chlorine and chloride feed rate screening limits determined under § 266.107 (b)(1) or (e).

* * * * *

(vi) Maximum production rate of the device in appropriate units when producing normal product, unless complying with the Tier I or Adjusted Tier I feed rate screening limits for chlorine under § 266.107 (b)(1) or (e) and for all metals under § 266.106 (b) or (e), and the uncontrolled particulate emissions do not exceed the standard under § 266.105.

* * * * *

(5) *Special requirements for HC monitoring systems.* When an owner or operator is required to comply with the hydrocarbon (HC) controls provided by § 266.104(c) or paragraph (a)(5)(i)(D) of this section, a conditioned gas monitoring system may be used in conformance with specifications provided in appendix IX of this part provided that the owner or operator submits a certification of compliance without using extensions of time provided by paragraph (c)(7) of this section. However, owners and operators of facilities electing to comply with the alternative hydrocarbon provision of § 266.104(f) and requesting a time extension under § 266.103(c)(7)(ii)(B) may establish the baseline HC level and comply with the interim HC limit established by the time extension using a conditioned gas monitoring system if the Director determines that the owner or operator has demonstrated that they have made a good faith effort to operate a heated monitoring system but found it to be impracticable.

* * * * *

(7) * * *

(ii) * * *

(B) When an owner or operator requests an extension of time to enable the facility to comply with the alternative hydrocarbon provisions of § 266.104(f) and obtain a RCRA operating permit because the facility cannot meet the HC limit of § 266.104(c) of this chapter:

* * * * *

5. Section 266.104 is amended by revising paragraph (f)(1) to read as follows:

§ 266.104 Standards to control organic emissions.

* * * * *

(f) * * *

(1) When the baseline HC (and CO) level is determined, the owner or operator must demonstrate that the facility is designed and operated to minimize hydrocarbon emissions from fuels and raw materials and that the facility is producing normal products under normal operating conditions feeding normal feedstocks and fuels. The baseline HC level is defined as the average over all valid test runs of the highest hourly rolling average HC value for each run when the facility does not burn hazardous waste, adjusted as appropriate to consider the variability of hydrocarbon levels under good combustion operating conditions. The baseline CO level is determined based on the test runs used to establish the baseline HC level and is defined as the average over all test runs of the highest hourly rolling average CO value for each run. More than one baseline level must be determined if the facility operates under different modes that may generate significantly lower HC (and CO) levels;

* * * * *

6. Section 266.106 is amended by revising paragraphs (b)(7) introductory text, (d)(1), (d)(5), and by revising the equation in paragraph (d)(3) to read as follows:

§ 266.106 Standards to control metals emissions.

* * * * *

(b) * * *

(7) *Criteria for facilities not eligible for screening limits.* If any criteria below are met, the Tier I and Tier II screening limits do not apply. Owners and operators of such facilities must comply with either the Tier III standards provided by paragraph (d) of this section or with the adjusted Tier I feed rate screening limits provided by paragraph (e) of this section.

* * * * *

(d) *Tier III and Adjusted Tier I site-specific risk assessment.* The requirements of this paragraph apply to facilities complying with either the Tier III or Adjusted Tier I controls, except where specified otherwise.

(1) *General.* Conformance with the Tier III metals controls must be demonstrated by emissions testing to determine the emission rate for each metal. In addition, conformance with either the Tier III or Adjusted Tier I metals controls must be demonstrated by air dispersion modeling to predict the maximum annual average off-site ground level concentration for each

dispersion modeling to predict the maximum annual average off-site ground level concentration for each metal, and a demonstration that acceptable ambient levels are not exceeded.

* * * * *

(3) * * *

$$\sum_{i=1}^{n} \frac{\text{Predicted Ambient Concentration}_{(i)}}{\text{Risk-Specific Dose}_{(i)}} \leq 1.0$$

* * * * *

(5) *Multiple stacks.* Owners and operators of facilities with more than one on-site stack from a boiler, industrial furnace, incinerator, or other thermal treatment unit subject to controls on metals emissions under a RCRA operating permit or interim status controls must conduct emissions testing (except that facilities complying with Adjusted Tier I controls need not conduct emissions testing) and dispersion modeling to demonstrate that the aggregate emissions from all such on-site stacks do not result in an exceedance of the acceptable ambient levels.

* * * * * *

7. Section 266.107 is amended by revising paragraph (a) to read as follows:

§ 266.107 Standards to control hydrogen chloride (HCl) and chlorine gas (Cl_2) emissions.

(a) General. The owner or operator must comply with the hydrogen chloride (HCl) and chlorine (Cl_2) controls provided by paragraph (b), (c), or (e) of this section.

* * * * *

8. Section 266.108(c) is amended by revising the equation to read as follows:

§ 266.108 Small quantity on-site burner exemption.

* * * * *

(c) * * *

$$\sum_{i=1}^{n} \frac{\text{Actual Quantity Burned}_{(i)}}{\text{Allowable Quantity Burned}_{(i)}} \leq 1.0$$

* * * * *

9. Section 266.112 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 266.112 Regulation of residues.

* * * * *

(b) * * *

(2) * * *

(i) *Nonmetal constituents.* The concentration of each nonmetal toxic constituent of concern (specified in paragraph (b)(1) of this section) in the waste-derived residue must not exceed the health-based level specified in appendix VII of this part, or the level of detection (using analytical procedures prescribed in SW–846), whichever is higher. If a health-based limit for a constituent of concern is not listed in appendix VII of this part, then a limit of 0.002 micrograms per kilogram or the level of detection (using analytical procedures prescribed in SW–846), whichever is higher, shall be used; and

* * * * *

Appendix IX [Amended]

10. In appendix IX, § 5.0, Hazardous Waste Combustion Air Quality Screening Procedure, Table 5.0–3.—Clarification of Land Use Types, footnote 1, revise "EPA–450/2–78–027" to read "EPA–450/2–78–027R".

11. In appendix IX, § 5.0, Hazardous Waste Combustion Air Quality Screening Procedure, in the title to Table 5.0–4, revise "ISCT" to read "ISCST", revise "PREDICATED" to read "PREDICTED", and revise "8G/M ^{3}" to read "g/m^3".

12. In appendix IX, § 5.0, Hazardous Waste Combustion Air Quality Screening Procedure, in the title to Table 5.0–5, revise "ISCT" to read "ISCST", revise "PREDICATED" to read "PREDICTED", and revise "8G/M ^{3}" to read "g/m^3".

13. In appendix IX, § 6.0—Simplified Land Use Classification Procedure for Compliance with Tier I and Tier II Limits, Subsection 6.1 Introduction: second paragraph, add a footnote "1" after "(EPA 1986)"; in footnote 1, revise "EPA–450/2–78–027" to read "EPA–450/2–78–027R"; and in the third paragraph, revise "Auer 3978" to read "Auer 1978".

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August 25, 1992

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310

Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 91N-0505]

RIN 0905-AA06

Status of Certain Additional Over-the Counter Drug Category II and III Active Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking stating that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA is issuing this notice of proposed rulemaking after considering the reports and recommendations of various OTC advisory review panels and public comments on the agency's proposed regulations, which were issued in the form of a tentative final monograph (proposed rule). Based on the absence of substantive comments in opposition to the agency's proposed nonmonograph status for these ingredients, as well as the failure of interested parties to submit new data or information to FDA pursuant to 21 CFR 330.10(a)(7)(iii), FDA has determined that the presence of these ingredients in an OTC drug product would result in that drug product not being generally recognized as safe and effective or would result in misbranding. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposal before the Commissioner of Food and Drugs by October 26, 1992. Written comments on the agency's economic impact determination by October 26, 1992.

ADDRESSES: Written comments, objections, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 7, 1990 (55 FR 46914), FDA published under § 330.10(a)(7)(ii) (21 CFR 330.10(a)(7)(ii)), a final rule on the status of certain OTC drug Category II and III active ingredients. That final rule declared as not generally recognized as safe and effective certain Category II and Category III active ingredients for which, under the agency's OTC drug review, the periods for submission of comments and new data following the publication of a notice of proposed rulemaking had closed and for which no significant comments or new data to upgrade the status of these ingredients had been submitted. In each instance, a final rule for the class of ingredients involved had not been published to date.

At that time, there were other OTC drug review rulemakings for which the period for submission of comments and/or new data was still pending. Those periods have now closed, and there are a number of active ingredients for which no significant comments or new data were submitted. In each instance, a final rule for the class of ingredients involved has not been published to date. This proposal addresses the Category II and Category III active ingredients in those classes of ingredients, as discussed below.

This proposal also addresses a number of active ingredients that were considered in the rulemaking for OTC digestive aid drug products. In the advance notice of proposed rulemaking for those drug products (47 FR 454, January 5, 1982), a number of ingredients are listed for which the Advisory Review Panel on OTC Miscellaneous Internal Drug Products was neither able to locate nor was aware of any significant body of data demonstrating safety and effectiveness. These ingredients were not included in the final rule discussed above that was published on November 7, 1990. No comments or data have been submitted for any of these ingredients. Based on this lack of data, the agency is proposing these ingredients to be nonmonograph for safety and effectiveness and is adding them to the list already included in 21 CFR 310.545.

Under the OTC drug review administrative procedures (§ 330.10(a)(7)(ii)), the Commissioner of Food and Drugs (the Commissioner) may publish a separate tentative order covering active ingredients that have been reviewed and may propose that these ingredients be excluded from an OTC drug monograph on the basis of the Commissioner's determination that they would result in a drug product not being generally recognized as safe and effective or would result in misbranding. This order may include active ingredients for which no substantial comments in opposition to the advisory panel's proposed classification and no new data and information were received pursuant to § 330.10(a)(6)(iv) (21 CFR 330.10(a)(6)(iv)). While § 330.10(a)(7)(ii) authorizes the publication of a separate tentative order immediately following the close of the comment period and new data period for an advance notice of proposed rulemaking, the Commissioner has waited in the case of these ingredients until after proposed rulemakings were published and the periods for submission of comments and new data have ended, to allow for the fullest possible opportunity for public comment and receipt of new data in support of upgrading the status of these ingredients.

As mentioned, no substantive comments or new date were submitted to support reclassification of any of these ingredients to monograph status. Therefore, before a final rule on each respective drug category is published, the Commissioner is proposing that these ingredients be found not generally recognized as safe and effective and that any OTC drug product containing any of these ingredients not be allowed to continue to be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. FDA has elected to act on these ingredients in advance of finalization of other monograph conditions in order to expedite completion of the OTC drug review. Manufacturers are encouraged to comply voluntarily at the earliest possible date.

Table I below lists the titles and docket numbers of the specific rulemakings containing active ingredients that are addressed in this document, together with the publication dates of the advance notice of proposed rulemaking (ANPRM) and the notice of proposed rulemaking (NPRM), as well as the closing dates for comments and submission of new data for each rulemaking. This proposal does not constitute a reopening of the administrative record or an opportunity to submit new data to any of the specified rulemakings. A citizen petition to reopen the administrative record of any specific rulemaking, whether or not such petition is accompanied by new data, will not be accepted as a comment to this rulemaking. Should an interested person submit a comment indicating that substantive comments or new data were previously submitted to the administrative record for any of the specified rulemakings, the agency will review the record for that rulemaking

and make a determination whether the affected ingredient shall continue to be evaluated under that specified rulemaking or be included in the final rule that will issue pursuant to this proposed rule.

FDA advises that the active ingredients discussed in this document (see Table II below) will not be included in the relevant final monographs because they have not been shown to be generally recognized as safe and effective for their intended use. The agency further advises that these ingredients should be eliminated from OTC drug products 6 months after the date of publication in the **Federal Register** of a final rule in this proceeding regarding their status, regardless of whether further testing is undertaken to justify future use, and regardless of whether the relevant OTC drug monographs have been finalized at that time. The OTC drug review administrative procedures provide that any new data and information submitted after the administrative record has closed following publication of a tentative final monograph (notice of proposed rulemaking), but prior to the establishment of a final monograph, will be considered by the Commissioner only after a final monograph has been published in the **Federal Register**, unless the Commissioner finds that good cause has been shown that warrants earlier consideration. (See 21 CFR 330.10(a)(7)(v).)

The agency points out that publication of a final rule under this proceeding does not preclude a manufacturer's testing an ingredient. New, relevant data can be submitted to the agency at a later date as the subject of a new drug application (NDA) that may provide for prescription or OTC marketing status. (See 21 CFR part 314.) As an alternative, where there are adequate data establishing general recognition of safety and effectiveness, such data may be submitted in an appropriate citizen petition to amend or establish a monograph, as appropriate. (See 21 CFR 10.30.)

TABLE I.—OTC DRUG RULEMAKINGS COVERED BY THIS NOTICE

Rulemaking and action	Publication date	Comment closing date	New data closing date
(1) Digestive Aid Drug Products: (Docket No. 81N–0106)			
ANPRM	January 5, 1982	July 5, 1982	Not Applicable (N/A).
NPRM	January 29, 1988	March 29, 1988	March 29, 1989.
(2) Topical Antifungal Drug Products:			
(i) Topical Antifungal Drug Products: (Docket No. 80N–0476)			
ANPRM	March 23, 1982	July 21, 1982	N/A.
NPRM	December 12, 1989	March 12, 1990	February 12, 1991.
(ii) Diaper Rash Drug Products: (Docket No. 80N–476D)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	June 20, 1990	December 17, 1990	August 20, 1991.
(3) External Analgesic Drug Products:			
(i) Diaper Rash Drug Products: (Docket No. 78N–301D)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	June 20, 1990	December 17, 1990	August 20, 1991.
(ii) Fever Blister and Cold Sore Treatment Drug Products: (Docket No. 78N–301F)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	January 31, 1990	May 31, 1990	April 1, 1991.
(iii) Insect Bite and Sting Drug Products: (Docket No. 78N–301P)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	October 3, 1989	January 31, 1990	December 3, 1990.
(iv) Poison Ivy, Poison Oak, and Poison Sumac Drug Products: (Docket No. 78N–301P)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	October 3, 1989	January 31, 1990	December 3, 1990.
(4) Internal Analgesic, Antipyretic Antirheumatic Drug Products: (Docket No. 77N–0094)			
ANPRM	July 8, 1977	February 6, 1978	N/A.
NPRM	November 16, 1988	May 16, 1989	January 16, 1990.
(5) Orally Administered Menstrual Drug Products: (Docket No. 82N–0165)			
ANPRM	December 7, 1982	April 6, 1983	N/A.
NPRM	November 16, 1988	March 16, 1989	January 16, 1990.
(6) Pediculicide Drug Products: (Docket No. 81N–0201)			
ANPRM	June 29, 1982	October 27, 1982	N/A.
NPRM	April 3, 1989	June 2, 1989	June 4, 1990.
(7) Skin Protectant Drug Products:			
(i) Astringent Drug Products: (Docket No. 78N–021A)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	April 3, 1989	June 2, 1989	June 4, 1990.
(ii) Diaper Rash Drug Products: (Docket No. 78N–021D)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	June 20, 1990	December 17, 1990	August 20, 1991.
(iii) Fever Blister and Cold Sore Treatment Drug Products: (Docket No. 78N–021F)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	January 31, 1990	May 31, 1990	April 1, 1991.
(iv) Insect Bite and Sting Drug Products: (Docket No. 78N–021P)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	October 3, 1989	January 31, 1990	December 3, 1990.
(v) Poison Ivy, Poison Oak, and Poison Sumac Drug Products: (Docket No. 78N–021P)			
ANPRM	September 7, 1982	January 5, 1983	N/A.
NPRM	October 3, 1989	January 31, 1990	December 3, 1990.

I. OTC Drug Category II and III Ingredients

Based on the criteria discussed above, FDA is proposing that the following ingredients are not generally recognized as safe and effective and are misbranded when labeled as OTC drugs for the following uses:

TABLE II.—INGREDIENTS COVERED BY THIS NOTICE

Rulemaking and ingredients	Ingredient classification	
	ANPRM	NPRM
(1) Digestive aid drug products:		
Alcohol	II	II
Aluminum hydroxide	II	III
Amylase	II	II
Anise seed	II	II
Aromatic powder	II	II
Asafetida	II	II
Aspergillus oryza enzymes	II	II
Bacillus acidophilus	II	II
Bean	II	II
Belladonna alkaloids	II	II
Belladonna leaves, powdered extract.	II	II
Betaine hydrochloride	II	II
Bismuth subcarbonate	II	II
Bismuth subgallate	II	II
Black radish powder	II	II
Buckthorn	II	II
Calcium gluconate	II	II
Capsicum	II	II
Capsicum, fluid extract of	II	II
Carbon	II	II
Cascara sagrada extract	II	II
Catechu, tincture	II	II
Catnip	II	II
Chamomile flowers	II	II
Charcoal, wood	II	II
Chloroform	II	II
Cinnamon oil	II	II
Cinnamon tincture	II	II
Citrus pectin	II	II
Cnicus benedictus (blessed thistle).	II	II
Diastase	II	II
Diastase malt	II	II
Dog grass	II	II
Elecampane	II	II
Ether	II	II
Fennel acid	II	II
Galega	II	II
Ginger	II	II
Glycine	II	II
Hectorite	II	II
Horsetail	II	II
Huckleberry	II	II
Hydrastis canadensis (golden seal).	II	II
Hydrastis fluid extract	II	II
Hydrochloric acid	II	II
Iodine	II	II
Iron ox bile	II	II
Johnswort	II	II
Juniper	II	II
Kaolin, colloidal	II	II
Knotgrass	II	II
Lactic acid	II	II
Lactose	II	II
Lavender compound, tincture of.	II	II
Linden	II	II
Lipase	II	II
Lysine hydrochloride	II	II
Mannitol	II	II
Mycozyme	II	II
Myrrh, fluid extract of	II	II
Nettle	II	II
Nickel-pectin	II	II
Nux vomica extract	II	II
Orthophosphoric acid	II	II
Papaya, natural	II	II
Pectin	II	II
Peppermint	II	II
Peppermint spirit	II	II
Phenacetin	II	II
Potassium bicarbonate	II	II
Potassium carbonate	II	II
Protease	II	II
Prolase	II	II
Rhubarb fluid extract	II	II
Senna	II	II
Sodium chloride	II	II
Sodium salicylate	II	II
Stem bromelain	II	II
Strawberry	II	II
Strychnine	II	II
Tannic acid	II	II
Trillium	II	II
Woodruff	II	II
(2) Topical antifungal drug products.—(i) Topical antifungal drug products:		
Alcloxa	III	III
Alum, potassium	III	III
Aluminum sulfate	III	III
Amyltricresols, secondary	III	III
Basic fuchsin	III	III
Benzethonium chloride	III	III
Benzoic acid	III	III
Benzoxiquine	III	III
Boric acid	III	III
Camphor	II	II
Candicidin	III	III
Chlorothymol	III	III
Coal tar	II	II
Dichlorophen	III	III
Menthol	II	II
Methylparaben	III	III
Oxyquinoline	III	III
Oxyquinoline sulfate	III	III
Phenol	II	III
Phenolate sodium	II	III
Phenyl salicylate	III	III
Propionic acid	III	III
Propylparaben	III	III
Resorcinol	II	II
Salicylic acid	III	III
Sodium borate	III	III
Sodium caprylate	III	III
Sodium propionate	III	III
Sulfur	III	III
Tannic acid	II	II
Thymol	II	II
Tolindate	II	II
Triacetin	III	III
Zinc caprylate	III	III
Zinc propionate	III	III
(ii) Diaper rash drug products-Any ingredient	N/A	II
(3) External analgesic drug products.—(i) Diaper rash drug products:		
Any ingredient	N/A	II
(ii) Fever blister and cold sore treatment drug products:		
Allyl isothiocyanate	N/A	III
Aspirin	N/A	III
Bismuth sodium tartrate	N/A	III
Camphor	N/A	III
Capsaicin	N/A	III
Capsicum	N/A	III
Capsicum oleoresin	N/A	III
Chloral hydrate	N/A	II
Chlorobutanol	N/A	III
Cyclomethycaine sulfate	N/A	III
Eucalyptus oil	N/A	III
Eugenol	N/A	III
Glycol salicylate	N/A	III
Hexylresorcinol	N/A	III
Histamine dihydrochloride	N/A	III
Menthol	N/A	III
Methapyrilene hydrochloride	N/A	II
Methyl nicotinate	N/A	III
Methyl salicylate	N/A	III
Pectin	N/A	III
Salicylamide	N/A	III
Strong ammonia solution	N/A	III
Tannic acid	N/A	III
Thymol	N/A	III
Tripelennamine hydrochloride.	N/A	III
Trolamine salicylate	N/A	III
Turpentine oil	N/A	III
Zinc sulfate	N/A	III
(iii) Insect bite and sting drug products:		
Alcohol	II	II
Alcohol, ethoxylated alkyl	II	II
Benzalkonium chloride	II	II
Calamine	II	II
Ergot fluidextract	II	II
Ferric chloride	II	II
Panthenol	N/A	III
Peppermint oil	II	II
Pyrilamine maleate	II	II
Sodium borate	II	II
Trolamine salicylate	III	III
Turpentine oil	II	II
Zinc oxide	II	II
Zirconium oxide	II	II
(iv) Poison ivy, poison oak, and poison sumac drug products:		
Alcohol	N/A	II
Aspirin	N/A	III
Benzethonium chloride	N/A	II
Benzocaine (0.5 to 1.25 percent).	N/A	III
Bithionol	N/A	II
Calamine	N/A	II
Cetalkonium chloride	N/A	II
Chloral hydrate	N/A	II
Chlorobutanol	N/A	III
Chlorpheniramine maleate	N/A	II
Creosote, beechwood	N/A	II
Cyclomethycaine sulfate	N/A	III
Dexpanthenol	N/A	III
Diperodon hydrochloride	N/A	II
Eucalyptus oil	N/A	II
Eugenol	N/A	III
Glycerin	N/A	II
Glycol salicylate	N/A	III
Hectorite	N/A	II
Hexylresorcinol	N/A	II
Hydrogen peroxide	N/A	II
Impatiens biflora tincture	N/A	II
Iron oxide	N/A	II
Isopropyl alcohol	N/A	II
Lanolin	N/A	II
Lead acetate	N/A	II
Merbromin	N/A	II
Mercuric chloride	N/A	II
Methapyrilene hydrochloride	N/A	II
Panthenol	N/A	III
Parethoxycaine hydrochloride.	N/A	II
Phenyltoloxamine dihydrogen citrate.	N/A	II

TABLE II.—INGREDIENTS COVERED BY THIS NOTICE—Continued

Rulemaking and ingredients	Ingredient classification	
	ANPRM	NPRM
Povidone-vinylacetate co-polymers.	N/A	II
Pyrilamine maleate	N/A	II
Salicylamide	N/A	III
Salicylic acid	N/A	II
Simethicone	N/A	II
Sulfur	N/A	II
Tannic acid	N/A	III
Thymol	N/A	III
Trolamine	N/A	II
Turpentine oil	N/A	II
Zirconium oxide	N/A	II
Zyloxin	N/A	II
(4) Internal analgesic drug products:		
Aminobenzoic acid [1]	II	II
Antipyrine	III	III
Aspirin, aluminum	III	III
Calcium salicylate	N/A	II
Codeine	II	II
Codeine phosphate	II	N/A
Codeine sulfate	II	N/A
Iodoantipyrine	II	II
Lysine aspirin	N/A	II
Methapyrilene fumarate [1]	III	II
Phenacetin	II	II
Pheniramine maleate [1]	III	III
Pyrilamine maleate [1]	III	III
Quinine	II	II
Salsalate	III	III
Sodium aminobenzoate [1]	II	II
(5) Orally administered menstrual drug products:		
Alcohol	II	II
Alfalfa leaves	II	II
Aloes	II	II
Asclepias tuberosa	II	II
Asparagus	II	II
Barosma	II	II
Bearberry (extract of uva ursi).	II	II
Bearberry fluidextract (extract of bearberry).	II	II
Blessed thistle (cnicus benedictus).	II	II
Buchu powdered extract (extract of buchu).	II	II
Calcium lactate	II	II
Calcium pantothenate	II	II
Capsicum oleoresin	II	II
Cascara fluidextract, aromatic (extract of cascara).	II	II
Chlorprophenpyridamine maleate.	II	II
Cimicifuga racemosa	II	II
Codeine	II	II
Collinsonia (extract stone root).	II	II
Corn silk	II	II
Couch grass	II	II
Dog grass extract	II	II
Ethyl nitrite	II	II
Ferric chloride	II	II
Ferrous sulfate	II	II
Gentiana lutea (gentian)	II	II
Glycyrrhiza glabra (licorice root).	II	II
Homatropine methylbromide	II	II
Hydrangea, powdered extract (extract of hydrangea).	II	II
Hydrastis canadensis (golden seal).	II	II
Hyoscyamine sulfate	II	II
Juniper oil (oil of juniper)	II	II
Magnesium sulfate	II	II
Methapyrilene hydrochloride	II	II

TABLE II.—INGREDIENTS COVERED BY THIS NOTICE—Continued

Rulemaking and ingredients	Ingredient classification	
	ANPRM	NPRM
Methenamine	II	II
Methylene blue	II	II
Natural estrogenic hormone	II	II
Niacinamide	II	II
Nutmeg oil (oil of nutmeg)	II	II
Oil of erigeron	II	II
Parsley	II	II
Peppermint spirit	II	II
Pepsin, essence	II	II
Phenacetin	II	II
Phenindamine tartrate	II	II
Phenyl salicylate	II	II
Piscidia erythrina	II	II
Pipsissewa	II	II
Potassium acetate	II	II
Potassium nitrate	II	II
Riboflavin	II	II
Saw palmetto	II	II
Senecio aureus	II	II
Sodium benzoate	II	II
Sodium nitrate	II	II
Sucrose	II	II
Sulfurated oils of turpentine	II	II
Taraxacum officinale	II	II
Theobromine sodium salicylate.	III	III
Theophylline	III	III
Thiamine hydrochloride	II	II
Triticum	II	II
Turpentine, venice (venice turpentine).	II	II
Urea	II	II
(6) Pediculicide drug products:		
Benzocaine	II	II
Benzyl alcohol	II	II
Benzyl benzoate	II	II
Chlorophenothane (dichlorodiphenyl trichloroethane).	II	II
Coconut oil soap, aqueous	II	II
Copper oleate	II	II
Docusate sodium	II	II
Formic acid [2]	N/A	N/A
Isobornyl thiocyanoacetate	II	II
Picrotoxin	II	II
Propylene glycol	II	II
Sabadilla alkaloids	II	II
Sulfur, sublimed	II	II
Thiocyanoacetate	II	II
(7) Skin protectant drug products.—(i) Astringent drug products:		
Acetone	II	II
Alcohol	II	II
Alum, ammonium	II	II
Alum, potassium	II	II
Aluminum chlorhydroxy complex.	II	II
Aromatics	II	II
Benzalkonium chloride	II	II
Benzethonium chloride	II	II
Benzocaine	II	II
Benzoic acid	II	II
Boric acid	II	II
Calcium acetate	II	II
Camphor gum	II	II
Clove oil	II	II
Colloidal oatmeal	II	II
Cresol	II	II
Cupric sulfate	II	II
Eucalyptus oil	II	II
Eugenol	II	II
Honey	II	II
Isopropyl alcohol	II	II
Menthol	II	II
Methyl salicylate	II	II
Oxyquinoline sulfate	II	II

TABLE II.—INGREDIENTS COVERED BY THIS NOTICE—Continued

Rulemaking and ingredients	Ingredient classification	
	ANPRM	NPRM
P-t-butyl-m-cresol	II	II
Peppermint oil	II	II
Phenol	II	II
Polyoxytheylene laurate	II	II
Potassium ferrocyanide	II	II
Sage oil	II	II
Silver nitrate	II	II
Sodium borate	II	II
Sodium diacetate	II	II
Talc	II	II
Tannic acid glycerite	II	II
Thymol	II	II
Topical starch	II	II
Zinc chloride	II	II
Zinc oxide	II	II
Zinc phenolsulfonate	II	II
Zinc stearate	II	II
Zinc sulfate	II	II
(ii) Diaper rash drug products:		
Aluminum hydroxide	N/A	III
Cocoa butter	N/A	III
Cysteine hydrochloride	N/A	III
Glycerin	N/A	III
Protein hydrolysate	N/A	III
Racemethionine	N/A	III
Sulfur	N/A	II
Tannic acid	N/A	II
Zinc acetate	N/A	III
Zinc carbonate	N/A	III
(iii) Fever blister and cold sore treatment drug products:		
Bismuth subnitrate	N/A	II
Boric acid	N/A	II
Pyridoxine hydrochloride	N/A	II
Sulfur	N/A	II
Tannic acid	N/A	III
Topical starch	N/A	III
Trolamine	N/A	III
Zinc sulfate	N/A	III
(iv) Insect bite and sting drug products:		
Alcohol	II	II
Alcohol, ethoxylated alkyl	II	II
Ammonia solution, strong	II	II
Ammonium hydroxide	III	III
Benzalkonium chloride	II	II
Camphor	II	II
Ergot fluidextract	II	II
Ferric chloride	II	II
Menthol	II	II
Peppermint oil	II	II
Phenol	II	II
Pyrilamine maleate	II	II
Sodium borate	II	II
Trolamine	III	III
Turpentine oil	II	II
Zirconium oxide	II	II
(v) Poison ivy, poison oak, and poison sumac drug products:		
Alcohol	N/A	II
Anion and cation exchange resins buffered.	III	III
Benzethonium chloride	N/A	II
Benzocaine	N/A	II
Benzyl alcohol	N/A	II
Bismuth subnitrate	N/A	II
Bithionol	N/A	II
Boric acid	N/A	II
Camphor	N/A	II
Cetalkonium chloride	N/A	II
Chloral hydrate	N/A	II
Chlorpheniramine maleate	N/A	II
Creosote	N/A	II
Diperodon hydrochloride	N/A	II
Diphenhydramine hydrochloride.	N/A	II

TABLE II.—INGREDIENTS COVERED BY THIS NOTICE—Continued

Rulemaking and ingredients	Ingredient classification	
	ANPRM	NPRM
Eucalyptus oil	N/A	II
Ferric chloride	II	II
Glycerin	N/A	II
Hectorite	N/A	II
Hydrogen peroxide	N/A	II
Impatiens biflora tincture	N/A	II
Iron oxide	N/A	II
Isopropyl alcohol	N/A	II
Lanolin	N/A	II
Lead acetate	N/A	II
Lidocaine	N/A	II
Menthol	N/A	II
Merbromin	N/A	II
Mercuric chloride	N/A	II
Panthenol	N/A	II
Parethoxycaine hydrochloride.	N/A	II
Phenol	N/A	II
Phenyltoloxamine dihydrogen citrate.	N/A	II
Povidone-vinylacetate copolymers.	N/A	II
Salicylic acid	N/A	II
Simethicone	N/A	II
Tannic acid	N/A	II
Topical starch	N/A	III
Trolamine	N/A	III
Turpentine oil	N/A	II
Zirconium oxide	N/A	II
Zyloxin	N/A	II

N/A Means that the ingredient was either not classified by the Panel or was not included in the indicated (ANPRM/NPRM) document.

[1] Ingredient used as an analgesic-antipyretic adjuvant.

[2] This ingredient was not submitted to or previously classified in the OTC drug review, but has been observed in a marketed product.

II. The Agency's Tentative Conclusions on Certain OTC Drug Category II and III Ingredients

The agency has determined that no substantive comments or additional data have been submitted to the OTC drug review to support any of the ingredients listed above as being generally recognized as safe and effective for the OTC drug uses specified in Table II. Based on the agency's procedural regulations (§ 330.10(a)(7)(ii)), the agency has determined that these ingredients should be deemed not generally recognized as safe and effective for OTC use before a final monograph for each respective drug category is established. Accordingly, any drug product containing any of these ingredients and labeled for the OTC use identified above will be considered nonmonograph and misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) and a new drug under section 201(p) of the act (21 U.S.C. 321(p)) for which an approved application under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 of the regulations is required for marketing. As an alternative, where there are adequate data establishing general recognition of safety and effectiveness, such data may be submitted in a citizen petition to amend the appropriate monograph to include any of the above ingredients in OTC drug products. (See 21 CFR 10.30.) Any OTC drug product containing any of the above ingredients and labeled for the use identified above initially introduced or initially delivered for introduction into interstate commerce after the effective date of a final rule in this proceeding to remove these Category II and III ingredients from the market and that is not the subject of an approved application will be in violation of sections 502 and 505 of the act and, therefore, subject to regulatory action. Further, any OTC drug product subject to the final rule that is repackaged or relabeled after the effective date of the rule would be required to be in compliance with the rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

The agency has examined the economic consequences of this proposed rulemaking. The agency invited public comment in the notices of proposed rulemaking listed in Table I regarding any impact that those rulemakings would have on drug products containing the above specified OTC drug ingredients. No comments on economic impacts were received. Moreover, manufacturers of products containing these ingredients have not provided any substantive data to support their continued marketing. Accordingly, the agency concludes that there is no basis for the continued marketing of these ingredients for the indications listed in Table II. Further, in most cases, there are proposed rulemaking ingredients which manufacturers can use to reformulate affected products. In many instances, manufacturers have already reformulated their products to include monograph ingredients. As a result of this proposal, manufacturers may need to reformulate some products prior to promulgation of the applicable final monograph. However, there will be no additional costs because reformulation will be required, in any event, when the final monograph is published.

Early finalization of the nonmonograph status of the ingredients listed in this notice will benefit both consumers and manufacturers. Consumers will benefit from the early removal from the marketplace of ingredients for which safety and effectiveness have not been established. This will result in a direct economic savings to consumers. Manufacturers will benefit from being able to use alternative ingredients that have been found to be generally recognized as safe and effective without incurring additional expense of clinical testing for these ingredients. Based on the above, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by October 26, 1992. Such comments should be submitted to the Dockets Management Branch (address above) and identified with the docket number found in brackets in the heading of this document and not to the docket numbers appearing in Table I. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before October 26, 1992, submit to the Dockets Management Branch (address above) written comments, objections, or requests for oral hearing before the Commissioner on the proposed rulemaking. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before October 26, 1992. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the appropriate docket number found in brackets in the heading of this document and not the docket numbers appearing in Table I, and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

List of Subjects in 21 CFR Part 310

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 310 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 376); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.545 is amended by redesignating paragraphs (a)(8) and (a)(18) as (a)(8)(i) and (a)(18)(i), respectively; by revising the heading of new paragraphs (a)(8)(i) and (a)(18)(i), (d) introductory text, and (d)(1); and by adding new (a)(8) heading and paragraphs (a)(8)(ii), (a)(10)(iv) through (a)(10)(vii), and (a)(18) heading, paragraphs (a)(18)(ii) through (a)(18)(vi), (a)(21)(i) and (a)(21)(ii), (a)(22) through (a)(24), and (d)(4) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(8) *Digestive aid drug products*—(i) *Approved as of May 7, 1991.* * * *

(ii) *Approved as of February 26, 1993.*

Alcohol
Aluminum hydroxide
Amylase
Anise seed
Aromatic powder
Asafetida
Aspergillus oryza enzymes
Bacillus acidophilus
Bean
Belladonna alkaloids
Belladonna leaves, powdered extract
Betaine hydrochloride
Bismuth subcarbonate
Bismuth subgallate
Black radish powder
Blessed thistle (cnicus benedictus)
Buckthorn
Calcium gluconate
Capsicum
Capsicum, fluid extract of
Carbon
Cascara sagrada extract
Catechu, tincture
Catnip
Chamomile flowers
Charcoal, wood
Chloroform
Cinnamon oil
Cinnamon tincture
Citrus pectin
Diastase
Diastase malt
Dog grass
Elecampane
Ether
Fennel acid
Galega
Ginger
Glycine
Golden seal (hydrastis canadensis)
Hectorite
Horsetail
Huckleberry
Hydrastis fluid extract
Hydrochloric acid
Iodine
Iron ox bile
Johnswort
Juniper
Kaolin, colloidal
Knotgrass
Lactic acid
Lactose
Lavender compound, tincture of
Linden
Lipase
Lysine hydrochloride
Mannitol
Mycozyme
Myrrh, fluid extract of
Nettle
Nickel-pectin
Nux vomica extract
Orthophosphoric acid
Papaya, natural
Pectin
Peppermint
Peppermint spirit
Phenacetin
Potassium bicarbonate
Potassium carbonate
Protease
Prolase
Rhubarb fluid extract
Senna
Sodium chloride
Sodium salicylate
Stem bromelain
Strawberry
Strychnine
Tannic acid
Trillium
Woodruff

* * * * *

(10) * * *

(iv) *Diaper rash drug products.* Any ingredient(s) labeled with claims or directions for use in the treatment and/or prevention of diaper rash.

(v) *Fever blister and cold sore treatment drug products.*

Allyl isothiocyanate
Asprin
Bismuth sodium tartrate
Camphor
Capsaicin
Capsicum oleoresin
Chloral hydrate
Chlorobutanol
Cyclomethycaine sulfate
Eucalyptus oil
Eugenol
Glycol salicylate
Hexylresorcinol
Histamine dihydrochloride
Menthol
Methapyrilene hydrochloride
Methyl nicotinate
Methyl salicylate
Pectin
Salicylamide
Strong ammonia solution
Tannic acid
Thymol
Tripelennamine hydrochloride
Trolamine salicylate
Turpentine oil
Zinc sulfate

(vi) *Insect bite and sting drug products.*

Alcohol
Alcohol, ethoxylated alkyl
Benzalkonium chloride
Calamine
Ergot fluidextract
Ferric chloride
Panthenol
Peppermint oil
Pyrilamine maleate
Sodium borate
Trolamine salicylate
Turpentine oil
Zinc oxide
Zirconium oxide

(vii) *Poison ivy, poison oak, and poison sumac drug products.*

Alcohol
Aspirin
Benzethonium chloride
Benzocaine (0.5 to 1.25 percent)
Bithionol
Calamine
Cetalkonium chloride
Chloral hydrate
Chlorobutanol
Chlorpheniramine maleate
Creosote, beechwood
Cyclomethycaine sulfate
Dexpanthenol
Diperodon hydrochloride
Eucalyptus oil
Eugenol
Glycerin
Glycol salicylate
Hectorite

Hexylrosorcinol
Hydrogen peroxide
Impatiens biflora tincture
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Merbromin
Mercuric chloride
Methapyrilene hydrochloride
Panthenol
Parethoxycaine hydrochloride
Phenyltoloxamine dihydrogen citrate
Povidone-vinylacetate copolymers
Pyrilamine maleateSalicylamide
Salicylic acid
Simethicone
Sulfur
Tannic acid
Thymol
Trolamine salicylate
Turpentine oil
Zirconicum oxide
Zyloxin

* * * * *

(18) *Skin protectant drug products*—(i) *Ingredients.* * * *

(ii) *Astringent drug products.*

Acetone
Alcohol
Alum, ammonium
Alum, potassium
Aluminum chlorhydroxy complex
Aromatics
Benzalkonium chloride
Benzethonium chloride
Benzocaine
Benzoic acid
Boric acid
Calcium acetate
Camphor gum
Clove oil
Colloidal oatmeal
Cresol
Cupric sulfate
Eucalyptus oil
Eugenol
Honey
Isopropyl alcohol
Menthol
Methyl salicylate
Oxyquinoline sulfate
P-t-butyl-m-cresol
Peppermint oil
Phenol
Polyoxytheylene laurate
Potassium ferrocyanide
Sage oil
Silver nitrate
Sodium borate
Sodium diacetate
Talc
Tannic acid glycerite
Thymol
Topical starch
Zinc chloride
Zinc oxide
Zinc phenolsulfonate
Zinc stearate
Zinc sulfate

(iii) *Diaper rash drug products.*

Aluminum hydroxide
Cocoa butter
Cysteine hydrochloride
Glycerin
Protein hydrolysate
Racemethionine
Sulfur
Tannic acid
Zinc acetate
Zinc carbonate

(iv) *Fever blister and cold sore treatment drug products.*

Bismuth subnitrate
Boric acid
Pyridoxide hydrochloride
Sulfur
Tannic acid
Topical starch
Trolamine
Zinc sulfate

(v) *Insect bite and sting drug products.*

Alcohol
Alcohol, ethoxylated alkyl
Ammonia solution, strong
Ammonium hydroxide
Benzalkonium chloride
Camphor
Ergot fluidextract
Ferric chloride
Menthol
Peppermint oil
Phenol
Pyrilamine maleate
Sodium borate
Trolamine
Turpentine oil
Zirconium oxide

(vi) *Poison ivy, poison oak, and poison sumac drug products.*

Alcohol
Anion and cation exchange resins buffered
Benzethonium chloride
Benzocaine
Benzyl alcohol
Bismuth subnitrate
Bithionol
Boric acid
Camphor
Cetalkonium chloride
Chloral hydrate
Chlorpheniramine maleate
Creosote
Diperodon hydrochloride
Diphenhydramine hydrochloride
Eucalyptus oil
Ferric chloride
Glycerin
Hectorite
Hydrogen peroxide
Impatiens biflora tincture
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Lidocaine
Menthol
Merbromin
Mercuric chloride
Panthenol
Parethoxycaine hydrochloride
Phenol
Phenyltoloxamine dihydrogen citrate
Povidone-vinylacetate copolymers
Salicylic acid
Simethicone
Tannic acid
Topical starch
Trolamine
Turpentine oil
Zirconium oxide
Zyloxin

* * * * *

(21) *Topical antifungal drug products.*

(i) *Ingredients.*

Alcloxa
Alum, potassium
Aluminum sulfate
Amyltricresols, secondary
Basic fuchsin
Benzethonium chloride
Benzoic acid
Benzoxiquine
Boric acid
Camphor
Candicidin
Chlorothymol
Coal tar
Dichlorophen
Menthol
Methylparaben
Oxyquinoline
Oxyquinoline sulfate
Phenol
Phenolate sodium
Phenyl salicylate
Propionic acid
Propylparaben
Resorcinol
Salicylic acid
Sodium borate
Sodium caprylate
Sodium propionate
Sulfur
Tannic acid
Thymol
Tolindate
Triacetin
Zinc caprylate
Zinc propionate

(ii) *Diaper rash drug products.* Any ingredient(s) labeled with claims or directions for use in the treatment and/or prevention of diaper rash.

(22) *Internal analgesic drug products.*

Aminobenzoic acid
Antipyrine
Aspirin, aluminum
Calcium salicylate
Codeine
Codeine phosphate

Codeine sulfate
Iodoantipyrine
Lysine aspirin
Methapyrilene fumarate
Phenacetin
Pheniramine maleate
Pyrilamine maleate
Quinine
Salsalate
Sodium aminobenzoate

(23) *Orally administered menstrual drug products.*

Alcohol
Alfalfa leaves
Aloes
Asclepias tuberosa
Asparagus
Barosma
Bearberry (extract of uva ursi)
Bearberry fluidextract (extract of bearberry)
Blessed thistle (cnicus benedictus)
Buchu powdered extract (extract of buchu)
Calcium lactate
Calcium pantothenate
Capsicum oleorisin
Cascara fluidextract, aromatic (extract of cascara)
Chlorprophenpyridamine maleate
Cimicifuga racemosa
Codeine
Collinsonia (extract stone root)
Corn silk
Couch grass
Dog grass extract
Ethyl nitrite
Ferric chloride
Ferrous sulfate
Gentiana lutea (gentian)
Glycyrrhiza (licorice)
Homatropine methylbromide
Hydrangea, powdered extract (extract of hydrangea)
Hydrastis canadensis
Hyoscyamine sulfate
Juniper oil (oil of juniper)
Magnesium sulfate
Methapyrilene hydrochloride
Methenamine
Methylene blue
Natural estrogenic hormone
Niacinamide
Nutmeg oil (oil of nutmeg)
Oil of erigeron
Parsley
Peppermint spirit
Pepsin, essence
Phenacetin
Phenindamine tartrate
Phenyl salicylate
Piscidia erythrina
Pipsissewa
Potassium acetate
Potassium nitrate
Riboflavin
Saw palmetto
Senecio aureus
Sodium benzoate
Sodium nitrate
Sucrose
Sulferated oils of turpentine
Taraxacum officinale
Theobromine sodium salicylate
Theophylline
Thiamine hydrochloride
Triticum
Turpentine, venice
Urea

(24) *Pediculicide drug products.*

Benzocaine
Benzyl alcohol
Benzyl benzoate
Chlorophenothane (Dichlorodiphenyl trichloroethane)
Coconut oil soap, aqueous
Copper oleate
Docusate sodium
Formic acid
Isobornyl thiocyanoacetate
Picrotoxin
Propylene glycol
Sabadilla alkaloids
Sulfur, sublimed
Thiocyanoacetate

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(4) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(8)(i), (a)(9) through (a)(10)(iii), (a)(11) through (a)(18)(i), and (a)(19) of this section.

* * * * *

(4) February 26, 1993, for products subject to paragraphs (a)(8)(ii), (a)(10)(iv) through (a)(10)(vii), (a)(18)(ii) through (a)(18)(vi), (a)(21)(i) and (a)(21)(ii), and (a)(22) through (a)(24) of this section.

Dated: August 19, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

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