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List of Subjects in 21 CFR Part 866

Biologics, laboratories, medical devices.

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 866 be amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 866.3305 is revised to read as follows:

§ 866.3305 Herpes simplex virus serological assays.

(a) *Identification.* Herpes simplex virus serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the assays consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome.

(b) *Classification.* (1) Class II (special controls). The device is classified as class II if the herpes simplex virus serological assay is type 1 and/or 2. The special control for the device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Type 1 and 2 Serological Assays.'' For availability of the guidance document, see § 866.1(e).

(2) Class III (premarket approval). The device is classified as class III if the herpes simplex virus serological assay is a type other than type 1 and/or 2.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established for the requirement for premarket approval for the devices described in paragraph (b)(2) of this section. See § 866.3.

Dated: December 21, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 06–173 Filed 1–6–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0051; FRL–8020–2]

RIN 2060–AJ78

National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period and announcement of a public hearing.

SUMMARY: EPA is announcing that the comment period on the proposed amendments to National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry, published on December 2, 2005, is being extended until February 23, 2006, and that a public hearing on the proposed amendments will be held on January 24, 2006.

DATES: *Comments.* The comment period has been extended from January 17, 2006. Comments must now be received on or before February 23, 2006.

Public Hearing. A public hearing is scheduled for January 24, 2006, from 10 a.m. until 5 p.m. Eastern Standard Time.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2002–0051, by one of the following methods:

- *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- E-mail: *a-and-r-docket@epa.gov*, Attention Docket ID No. EPA–HQ–OAR–2002–0051.
- Fax: (202) 566–1741, Attention Docket ID No. EPA–HQ–OAR–2002–0051.
- Mail: U.S. Postal Service, send comments to: EPA Docket Center (6102T), Attention Docket ID No. EPA–HQ–OAR–2002–0051, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.
- Hand Delivery: In person or by courier, deliver comments to: EPA Docket Center (6102T), Attention Docket ID No. EPA–HQ–OAR–2002–0051, 1301 Constitution Avenue, NW., Room B–108, Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. Please include a total of two copies.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2002–0051. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. Send or deliver information identified as CBI to only the following address: Mr. Roberto Morales, OAQPS Document Control Officer, EPA (C404–02), Attention Docket ID No. EPA–HQ–OAR–2002–0051, Research Triangle Park, NC 27711. Clearly mark the part or all of the information that you claim to be CBI. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket. All documents in the docket are listed in the *http://www.regulations.gov index.* Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket Center, Docket ID No. EPA–HQ–OAR–2002–0051, EPA West Building, Room B–102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742. A reasonable fee may be charged for copying docket materials.

Public Hearing. The public hearing will be held on January 24, 2006, from 10 a.m. until 5 p.m. at the EPA Facility Complex at 109 T.W. Alexander Drive in Research Triangle Park, North Carolina. Persons interested in presenting oral testimony should contact Ms. Janet Eck, EPA, Office of Air Quality Planning and Standards, Emission Standards Division, Coatings and Consumer Products Group (C539–03), Research Triangle Park, NC 27711, telephone (919) 541–7946.

FOR FURTHER INFORMATION CONTACT: Mr. Keith Barnett, EPA, Office of Air Quality Planning and Standards, Emission Standards Division, Minerals and Inorganic Chemicals Group (C504–05), Research Triangle Park, NC 27711; telephone number (919) 541–5605; facsimile number (919) 541–5600; e-mail address *barnett.keith@epa.gov*.

SUPPLEMENTARY INFORMATION:

Regulated Entities. Entities potentially affected by the proposed amendments to the national emission standards for hazardous air pollutants (NESHAP) for the manufacturing of portland cement are those that manufacture portland cement. Regulated categories and entities include:

TABLE 1.—REGULATED ENTITIES TABLE

Category	NAICS [1]	Examples of regulated entities
Industry	32731 ..	Owners or operators of portland cement manufacturing plants.
State	32731 ..	Owners or operators of portland cement manufacturing plants.
Tribal Associations	32731 ..	Owners or operators of portland cement manufacturing plants.
Federal Agencies	[2]	None.

[1] North American Industry Classification System.
[2] None.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that may potentially be regulated by this action. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in 40 CFR 63.1340 of the rule. If you have questions regarding the applicability of the proposed amendments to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Submitting CBI. Do not submit this information through *http://www.regulations.gov* or e-mail. Send or deliver information identified as CBI only to the following address listed in the **ADDRESSES** section of this document. Clearly mark the part or all the information you claim to be CBI. For CBI information submitted on a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as

CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of today's proposal will also be available through the WWW. Following the Administrator's signature, a copy of this action will be posted on EPA's Technology Transfer Network (TTN) policy and guidance page for newly proposed or promulgated rules at *http://www.epa.gov/ttn/oarpg/.* The TTN at EPA's Web site provides information and technology exchange in various areas of air pollution control.

Comment Period

We received a request to move the date for a public hearing on the proposed amendments to the NESHAP for portland cement manufacturing (70 FR 72330, December 2, 2005) from mid-December 2005 to January 24, 2006. We agreed to this request and are extending the comment period until 30 days after the public hearing. Therefore, the public comment period will now end on February 23, 2006, rather than January 17, 2006.

How Can I Get Copies of the Proposed Amendments and Other Related Information?

EPA has established the official public docket for the proposed rulemaking under docket ID No. EPA–HQ–OAR–2002–0051. Information on how to access the docket is presented above in the **ADDRESSES** section. In addition, information may be obtained from the Web page for the proposed rulemaking at: *http://www.epa.gov/ttn/atw/pcem/pcempg.html.*

Dated: January 3, 2006.

William L. Wehrum,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 06–157 Filed 1–6–06; 8:45 am]

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