

inoperative. Section 63.850 of the final standard includes these provisions, except that the existing performance specifications for continuous emission monitors (CEMs) are not applicable to hydrogen fluoride CEMs because such specifications have not yet been developed for that device. In addition, all sources are required to submit quarterly and semiannual reports.

**Burden Statement:** In the most previously approved ICR, the estimated number of respondents for the information collection was 23 with 50 responses per year, and the annual industry reporting and recordkeeping burden for this collection of information was 121,277 hours. On the average, each respondent reported two times per year and spent 2,416 hours preparing each response.

The total annualized cost over its expected useful life is approximately \$117,000, which is comprised of zero capital/startup costs and operation and maintenance costs of approximately \$117,000. It is estimated that no new sources per year will become subject to the standard, but one existing source per year will add a new affected facility.

(8) NESHAP for Epoxy Resin and Non-Nylon Polyamide Production (40 CFR Part 63, Subpart W); EPA Preliminary ICR Number 1681.05; OMB Control Number 2060-0290; expiration date September 30, 2004.

**Affected Entities:** Entities potentially affected by this action are all existing, new, and reconstructed manufacturers of basic liquid epoxy resins and epichlorohydrin-modified non-nylon polyamide resins, also known as wet strength resins.

**Abstract:** The NESHAP for Epoxy Resin and Non-Nylon Polyamide Production (40 CFR Part 63, Subpart W), was promulgated on March 8, 1995, and amended on May 8, 2000.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports, and owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative.

**Burden Statement:** In the most previously approved ICR, the estimated number of respondents for this information collection was 13 with 29 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 4,525 hours. On the average, each respondent reported two times per year and spent 156 hours preparing each response.

The total annualized cost over its expected useful life is approximately \$9,000, which is comprised of zero capital/startup costs and operation and maintenance costs of approximately \$9,000. It is estimated that no additional sources will become subject to the standard over the next three years.

(9) NSPS for Sewage Sludge Treatment Plants (40 CFR Part 60, Subpart O); EPA Preliminary ICR Number 1063.09; OMB Control Number 2060-0035; expiration date September 30, 2004.

**Affected Entities:** Entities potentially affected by this action are each incinerator that combusts wastes containing more than 10 percent sewage sludge (dry basis) produced by municipal sewage treatment plants, or each incinerator which charges more than 1000 kg (2205 lb.) per day municipal sewage sludge (dry basis).

**Abstract:** The NSPS for Sewage Treatment Plants (40 CFR Part 60, Subpart O) were promulgated on February 28, 1974, and amended October 6, 1975, November 10, 1977, October 6, 1988, and October 17, 2000. The monitoring, recordkeeping, and reporting requirements outlined in the standards are mandatory for compliance with 40 CFR Part 60, NSPS for sewage sludge treatment plant incinerators.

The control of emissions of particulate matter from sewage treatment plant incinerators requires not only the installation of properly designed equipment, but also the operation and maintenance of that equipment.

These standards require initial notification reports with respect to construction, modification, reconstruction, startups, shutdowns, and malfunctions. The standards also require reports on initial performance tests and semiannual reports of excess emissions are also required.

**Burden Statement:** In the most previously approved ICR, the estimated number of respondents for this information collection was 154 with 294 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 9,089 hours. On the average, each respondent reported two times per year and spent 31 hours preparing each response.

The total annualized cost over its expected useful life are approximately \$5,845,000. The total annualized capital/startup cost is \$700,000, and the annualized operation and maintenance costs are approximately \$5,145,000.

Dated: October 20, 2003.

**Michael M. Stahl,**

*Director, Office of Compliance.*

[FR Doc. 03-27555 Filed 10-31-03; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[AMS-FRL-7582-4]

### California State Motor Vehicle Pollution Control Standards; Request for Waiver of Federal Preemption; Opportunity for Public Hearing

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of opportunity for public hearing and comment.

**SUMMARY:** The California Air Resources Board (CARB) has notified the EPA that it has promulgated regulations controlling emissions from off-cycle aggressive driving and air-conditioning usage for motor vehicles under 8,501 pounds gross vehicle weight rating with a phase-in of the requirements commencing in the 2001 model year. By letter dated January 29, 1999, CARB requests that the EPA provide California with a waiver of Federal preemption under section 209(b) of the Clean Air Act, 42 U.S.C. 7543(b), for these new test procedures and standards. Specifically, CARB's regulations adopt the two supplemental federal test procedures (SFTP)—the US06, high-speed, high-acceleration test; and the SC03 air conditioner test, and associated certification standards. This notice announces that EPA has tentatively scheduled a public hearing concerning California's request and that EPA is accepting comments on CARB's request.

**DATES:** EPA has tentatively scheduled a public hearing for December 3, 2003, beginning at 10 a.m. EPA will hold a hearing only if a party notifies EPA by November 24, 2003, expressing its interest in presenting oral testimony regarding CARB's waiver request. By November 28, 2003, any person who plans to attend the hearing should call David Dickinson of the EPA's Certification and Compliance Division at (202) 564-9256, to learn if we will hold a hearing. Any party may submit written comments by December 3, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, by facsimile, or through hand delivery/courier. Follow the detailed instructions as provided in section "B" of the **SUPPLEMENTARY INFORMATION** section. EPA will make available for public inspection at the Air and Radiation

Docket at EPA's Docket Center written comments received from interested parties, in addition to any testimony given at the public hearing. The reference number for this docket is OAR-2003-0187. Parties wishing to present oral testimony at the public hearing should provide written notice to David Dickinson at: U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., (6405J), Washington, DC 20460. Telephone: (202)564-9256. If EPA receives a request for a public hearing, the public hearing will be held in the first floor conference room at 501 3rd Street, NW., Washington, DC.

#### SUPPLEMENTARY INFORMATION:

##### A. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket OAR-2003-0187. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 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 Air and Radiation Docket is (202) 566-1743.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is

restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section "A.1."

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

##### B. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD-ROM you submit, and in any cover letter accompanying the disk or CD-ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select "Information Sources," "Dockets," and "EPA Dockets." Once in the system, select "search," and then key in Docket ID No. OAR-2003-0187. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by electronic mail (e-mail) to [www.A-and-R-docket.epa.gov](http://www.A-and-R-docket.epa.gov), Attention Docket ID No. OAR-2003-0187. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD-ROM.* You may submit comments on a disk or CD-ROM that you mail to the mailing address identified in section "A. 1." These electronic submissions will be accepted

in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send your comments to: U.S. Environmental Protection Agency, EPA West (Air Docket), 1200 Pennsylvania Avenue, NW., Room B108 Mailcode: 6102T, Washington, DC 20460, Attention Docket ID No. OAR-2003-0187

3. *By Hand Delivery or Courier.* Deliver your comments to: EPA Docket Center (Air Docket), Environmental Protection Agency, 1301 Constitution Avenue, NW., Room B108, Washington, DC 20004, Attention Docket ID No. OAR-2003-0187. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section "A.1."

4. *By Facsimile.* Fax your comments to: (202) 566-1742, Attention Docket ID No. OAR-2003-0187.

### C. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send or deliver information identified as CBI only to the addresses noted in B. 2 or B. 3 above, Attention Docket ID No. OAR-2003-0187. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD-ROM, 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 CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any 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 and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD-ROM, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

### D. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

### E. Background and Discussion

Section 209(a) of the Clean Air Act, as amended ("Act"), 42 U.S.C. 7543(a), provides:

No State or any political subdivision thereof shall adopt or attempt to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part. No state shall require certification, inspection or any other approval relating to the control of emission from any new motor vehicle or new motor vehicle engine as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment.

Section 209(b)(1) of the Act requires the Administrator, after notice and opportunity for public hearing, to waive application of the prohibitions of section 209(a) for any State that has adopted standards (other than crankcase emission standards) for the control of emissions from new motor vehicles or new motor vehicle engines prior to March 30, 1966, if the State determines that the State standards will be, in the aggregate, at least as protective of public health and welfare as applicable federal standards. California is the only State that is qualified to seek and receive a waiver under section 209(b). The Administrator must grant a waiver unless he finds that (A) the determination of the State is arbitrary and capricious, (B) the State does not need the State standards to meet compelling and extraordinary conditions, or (C) the State standards and accompanying enforcement procedures are not consistent with section 202(a) of the Act.

CARB's January 29, 1999, letter to the Administrator notified EPA that it had adopted new standards and test

procedures to control emissions from aggressive driving and air conditioning use. This regulatory action consisted of amendments to CARB's regulations found at 13 California Code of Regulations 1960.1, 2062, and 2101 and the incorporated "California Exhaust Emission Standards and Test Procedures for 1988 and Subsequent Model Passenger Cars, Light-Duty Trucks and Medium-Duty Vehicles," "California New Vehicle Compliance Test Procedure," and "California Assembly-Line test Procedures for 1998 and Subsequent Model Year Passenger Cars, Light-Duty Trucks, and Medium-Duty Vehicles."

EPA invites comment on the following issues: Whether (a) California's determination that its standards (including its new test procedures and associated standards noted above and in its January 29, 1999, request letter) are at least as protective of public health and welfare as applicable federal standards is arbitrary and capricious, (b) California needs separate standards to meet compelling and extraordinary conditions, and (c) California's standards and accompanying enforcement procedures are consistent with section 202(a) of the CAA?

### Procedures for Public Participation

In recognition that public hearings are designed to give interested parties an opportunity to participate in this proceeding, there are no adverse parties as such. Statements by participants will not be subject to cross-examination by other participants without special approval by the presiding officer. The presiding officer is authorized to strike from the record statements that he or she deems irrelevant or repetitious and to impose reasonable time limits on the duration of the statement of any participant.

If hearing(s) are held, the Agency will make a verbatim record of the proceedings. Interested parties may arrange with the reporter at the hearing(s) to obtain a copy of the transcript at their own expense. Regardless of whether public hearing(s) are held, EPA will keep the record open until December 3, 2003. Upon expiration of the comment period, the Administrator will render a decision on CARB's request based on the record of the public hearing(s), if any, relevant written submissions, and other information that he deems pertinent.

Dated: October 20, 2003.

**Robert Brenner,**

*Acting Assistant Administrator for Air and Radiation.*

[FR Doc. 03-27554 Filed 10-31-03; 8:45 am]

BILLING CODE 6560-50-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register**.

The Secretary of the Treasury has certified a rate of 12% for the quarter ended September 30, 2003. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: October 27, 2003.

**George Strader,**

*Deputy Assistant Secretary, Finance.*

[FR Doc. 03-27594 Filed 10-31-03; 8:45 am]

BILLING CODE 4150-04-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1998D-0896]

#### Guidance for Industry and Food and Drug Administration Staff; Premarket Approval Application Modular Review; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Premarket Approval Application Modular Review." This

guidance document is intended to provide industry and FDA staff with information regarding the premarket approval application (PMA) modular review program. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Premarket Approval Application Modular Review" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Nicole Wolanski, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

This guidance document provides FDA's recommendations about the content of a modular PMA and the procedures for submitting and reviewing a modular PMA. This document supersedes and replaces the guidance document entitled "Guidance for the Medical Device Industry on PMA Shell Development and Modular Review" issued on November 6, 1998.

FDA is making this guidance effective immediately because there is a statutory requirement that requires immediate implementation, and guidance is needed to help effect such implementation. On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law. Section 209 of MDUFMA amended section 515(c) of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 360e(c)), to codify FDA's modular review program for PMAs and authorize FDA to assess user fees for modular PMAs. In developing this guidance, the agency has considered its experience with its modular review program and comments on the topic that were submitted to the public docket on MDUFMA Implementation (Docket No. 02N-0534 (68 FR 5643, February 4, 2003)).

#### II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on modular PMAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

#### III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing PMAs (21 CFR part 814, OMB control number 0910-0231).

#### IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments on the guidance at any time. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### V. Electronic Access

To receive a copy of "Premarket Approval Application Modular Review" by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (835) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.