Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 98N–0171]

Medical Devices; Humanitarian Use of Devices; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend certain regulations governing humanitarian use devices. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. The amendments are being made to implement provisions of the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This companion proposed rule is being issued under FDAMA and the act as amended.

DATES: Comments must be received on or before July 1, 1998. Comments on the information collection requirements must be received on or before June 16, 1998.

ADDRESSES: Submit written comments on the companion proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The direct final rule and this companion proposed rule are substantively identical. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comments. A detailed discussion of this rule is set forth in the preamble of the direct final rule. If no significant comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation notice within 30 days after the comment period ends confirming that the direct final rule will go into effect on August 31, 1998. Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives any significant adverse comment regarding this rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rules's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending a rule change in addition to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiative, and it is intended to reduce the burden of unnecessary regulations on medical devices without diminishing the protection of public health.

Section 520(m) of the act (21 U.S.C. 360j(m)) was added by the Safe Medical Devices Act of 1990 (Pub. L. 101–629). Section 520(m) creates an incentive for the development of humanitarian use devices (HUD) for use in the treatment or diagnosis of diseases or conditions affecting a small number of individuals. Section 520(m) of the act authorizes FDA, by regulation, to exempt a HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) (i.e., ''reasonable assurance that the device is effective'') provided that: (1) The device is to be used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) the device would not be available to a person with such a disease or condition unless the exemption is granted; (3) no comparable device (other than a device that has been granted such an exemption) is available to treat or diagnose the disease or condition; and (4) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices to alternative forms or treatments.

In the **Federal Register** of June 26, 1996 (61 FR 33232), FDA published a final rule prescribing the procedures for submitting humanitarian device exemption (HDE) applications, amendments, and supplements; procedures for obtaining an extension of the exemption; and the criteria for FDA review and approval of HDE's. This rule amended part 814 (21 CFR part 814) of FDA's regulations.

On November 21, 1997, the President signed FDAMA into law. Section 203 of

FDAMA made the following changes to section 520(m) of the act:

(1) FDAMA added a new provision to section 520(m) of the act that requires FDA to issue an order approving or denying an HDE within 75 days after receiving the application.

(2) FDAMA provided for an exemption from the requirement that a HUD may not be used without approval from an institutional review board (IRB) for cases in which a physician determines in an emergency situation that approval cannot be obtained in time to prevent serious harm or death to a patient. In such cases, the physician must, after use of the device, notify the chairperson of the IRB. This notification must include the name of the patient, the date on which the device was used, and the reason for the use.

(3) FDAMA eliminated the requirement that the sponsor of an HDE obtain approval for continued use after 18 months. Instead, FDA may require a sponsor to demonstrate continued compliance with the requirements of section 520(m) of the act, if FDA believes that such a demonstration is necessary to protect the public health, or if FDA has reason to believe that the criteria for exemption are no longer met.

(4) FDAMA added a provision to section 520(m) of the act that FDA may withdraw an HDE approval only after providing notice and an opportunity for an informal hearing.

(5) FDAMA eliminated the ''sunset'' provision in section 520(m) of the act under which new approvals of HDE's would not have been permitted 5 years after the effective date of the rule originally implementing section 520(m).

FDA is issuing this companion proposed rule to amend the existing regulations to conform to revised section 520(m) of the act. For a discussion of the specific provisions of the regulation, see the preamble to the direct final rule published elsewhere in this issue of the **Federal Register**.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this proposed action is of a type that does not individually of cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impact of this companion proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule codifies applicable statutory requirements imposed by FDAMA. Because the companion proposed rule allows physicians more flexibility without compromising the public health and reduces the requirements imposed on sponsors, it may permit more small competitors to enter the marketplace. The agency, therefore, certifies that this proposed rule if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more in either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

This companion proposed rule 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 title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Amendments to Humanitarian Use Device Requirements.

Description: Section 520(m) of the act was created as an incentive for the development of HUD's for use in the treatment or diagnosis of diseases or conditions affecting fewer than 4,000 individuals in the United States. FDA is issuing this rule to propose amending the existing regulations governing HUD's found in part 814, to conform to the amendments made by FDAMA to section 520(m) of the act.

Section 814.124(a) would allow physicians in emergency situations to administer a HUD prior to obtaining IRB approval. In such situations, the physician would be required to provide written notification, including the identification of the patient involved, the date of use, and the reason for use, to the IRB within 5 days after emergency use. FDA anticipates that five physicians will use HUD's in emergency situations before obtaining approval from an IRB. FDA estimates that notifications under this section will take an average of 1 hour per response.

FDA is proposing to amend § 814.126(b)(1) to delete the requirement for a final report and to include an annual reporting requirement for HDE holders that will permit the agency to obtain sufficient information for it to determine whether there is reason to question the continued exemption of the device from the act's effectiveness requirements. FDA estimates that 15 HDE holders will submit annual reports. FDA believes that much of the information will already be in the HDE holder's possession, and the agency estimates that reports will take an average of 120 hours per response.

In addition to the changes required by FDAMA, FDA is proposing to amend § 814.104(b)(5) to allow a sponsor who is charging more than $250 per HUD to submit, in lieu of a report by an independent certified public accountant (CPA), an attestation by a responsible individual of the organization, verifying that the amount charged does not exceed the device's cost of research, development, fabrication, and distribution. In addition, the proposed

amendments to § 814.104(b)(5) would waive the requirement for submission of any CPA report or attestation for HUD's for which an HDE applicant is charging $250 or less. FDA anticipates, based on past experience, that 7 of the anticipated 15 HDE holders per year will charge less than $250 per HUD, and thus be exempt from the § 814.104(b)(5) requirement altogether. For the remaining eight HDE holders, FDA anticipates that all will submit attestations in lieu of CPA reports, and estimates that these submissions will require 2 hours to complete.

Section 814.126(b)(2) would modify the current recordkeeping requirement for HDE holders to require that HDE holders retain records indefinitely instead of only for the duration of the period for which the HUD is approved for marketing. FDA believes that this change will not affect the total time required to maintain the records.

Description of Respondents: Business or other for profit organizations.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.104(b)(5)	8	1	8	2	16
814.124(a)	5	1	5	1	5
814.126(b)(1)	15	1	15	120	1,800
Total					1,821

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.126(b)(2)	15	1	15	2	30

[1]There are no operating and maintenance costs or capital costs associated with this information collection.

For consistency with the direct final rule to which this proposed rule is a companion, FDA is following the PRA comment procedures for direct final rules in this proposed rule. As provided in 5 CFR 1320.5(c)(1), collections of information in a direct final rule are subject to the procedures set forth in 5 CFR 1320.10. Interested persons and organizations may submit comments on the information collection provisions of this proposed rule by June 16, 1998, to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit the provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of the direct final rule, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

V. Submission of Comments

Interested persons may, on or before July 1, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. This comment period runs concurrently with the comment period for the direct final rule. Two copies of any comments are to be submitted 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the direct final rule and this proposed rule. In the event, the direct final rule is withdrawn, all comments received will be considered comments on this proposed rule.

List of Subjects 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

2. Section 814.100 is amended by revising paragraphs (a)(2) and (d) and by adding new paragraph (e) to read as follows:

§ 814.100 Purpose and scope.

(a) * * *

(2) Marketing approval for the HUD notwithstanding the absence of reasonable assurance of effectiveness that would otherwise be required under sections 514 and 515 of the act.

* * * * *

(d) A person granted an exemption under section 520(m) of the act shall submit an annual report as described in § 814.126 (b).

(e) FDA may suspend or withdraw approval of an HDE after providing notice and an opportunity for an informal hearing.

3. Section 814.104 is amended by removing paragraph (b) and redesignating paragraphs (c) through (e) as paragraphs (b) through (d), by revising redesignated paragraph (b)(5) and the first sentence in redesignated paragraph (c), and by revising redesignated paragraph (d) to read as follows:

§ 814.104 Original applications.

* * * * *

(b) * * *

(5) The amount to be charged for the device and, if the amount is more than $250.00, a report by an independent certified public accountant, made in accordance with the Statement on Standards for Attestation established by the American Institute of Certified Public Accountants, or in lieu of such a report, an attestation by a responsible individual of the organization, verifying that the amount charged does not exceed the costs of the device's research, development, fabrication, and distribution. If the amount charged is $250.00 or less, the above requirement will be waived.

(c) *Omission of information.* If the applicant believes that certain information required under paragraph (b) of this section is not applicable to the device that is the subject of the HDE, and omits any such information from its HDE, the applicant shall submit a statement that identifies and justifies the omission. * * *

(d) *Address for submissions and correspondence.* Copies of all original HDE's, amendments and supplements, as well as any correspondence relating to an HDE, shall be sent or delivered to the Document Mail Center (HFZ–401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

4. Section 814.106 is revised to read as follows:

§ 814.106 HDE amendments and resubmitted HDE's.

An HDE or HDE supplement may be amended or resubmitted upon an applicant's own initiative, or at the request of FDA, for the same reasons and in the same manner as prescribed for PMA's in § 814.37, except that the timeframes set forth in § 814.37(c)(1) and (d) do not apply. If FDA requests an HDE applicant to submit an HDE amendment, and a written response to FDA's request is not received within 75 days of the date of the request, FDA will consider the pending HDE or HDE supplement to have been withdrawn voluntarily by the applicant. Furthermore, if the HDE applicant, on its own initiative or at FDA's request, submits a major amendment as described in § 814.37(c)(1), the review period may be extended up to 75 days.

5. Section 814.108 is revised to read as follows:

§ 814.108 Supplemental applications.

After FDA approval of an original HDE, an applicant shall submit supplements in accordance with the requirements for PMA's under § 814.39, except that a request for a new indication for use of a HUD shall comply with requirements set forth in § 814.110. The timeframes for review of and FDA action on an HDE supplement are the same as those provided in § 814.114 for an HDE.

6. Section 814.112 is amended by revising the introductory text of paragraph (a) and by revising paragraph (b) to read as follows:

§ 814.112 Filing an HDE.

(a) The filing of an HDE means that FDA has made a threshold determination that the application is sufficiently complete to permit substantive review. Within 30 days from the date an HDE is received by FDA, the agency will notify the applicant whether the application has been filed. FDA may refuse to file an HDE if any of the following applies:

* * * * *

(b) The provisions contained in § 814.42 (b), (c), and (d) regarding notification of filing decisions, filing dates, the start of the 75-day review period, and applicant's options in response to FDA refuse to file decisions shall apply to HDE's.

7. Section 814.114 is revised to read as follows:

§ 814.114 Timeframes for reviewing an HDE.

Within 75 days after receipt of an HDE that is accepted for filing and to which the applicant does not submit a major amendment, FDA will send the applicant an approval order, an approvable letter, a not approvable letter (under § 814.116), or an order denying approval (under § 814.118).

8. Section 814.116 is amended by revising the last sentence in paragraph (a), adding a sentence to the end of paragraph (a), revising the last sentence of paragraph (d), and adding paragraph (e) to read as follows:

§ 814.116 Procedures for review of an HDE.

(a) * * * If the HDE is referred to a panel, the agency shall follow the procedures set forth under § 814.44, with the exception that FDA will complete its review of the HDE and the advisory committee report and recommendations within 75 days from receipt of an HDE that is accepted for filing under § 814.112 or the date of filing as determined under § 814.106, whichever is later. Within the later of these two timeframes, FDA will issue an approval order under paragraph (b) of this section, an approvable letter under paragraph (c) of this section, a not approvable letter under paragraph (d) of this section, or an order denying approval of the application under § 814.118(a).

* * * * *

(d) * * * The applicant may respond to the not approvable letter in the same manner as permitted for not approvable letters for PMA's under § 814.44(f), with the exception that if a major HDE amendment is submitted, the review period may be extended up to 75 days.

(e) FDA will consider an HDE to have been withdrawn voluntarily if:

(1) The applicant fails to respond in writing to a written request for an amendment within 75 days after the date FDA issues such request;

(2) The applicant fails to respond in writing to an approvable or not approvable letter within 75 days after the date FDA issues such letter; or

(3) The applicant submits a written notice to FDA that the HDE has been withdrawn.

9. Section 814.118 is amended by revising paragraph (e) to read as follows:

§ 814.118 Denial of approval or withdrawal of approval of an HDE.

* * * * *

(e) Unless FDA otherwise determines that continued marketing under the HDE is inconsistent with the intent of section 520(m) of the act, FDA will not withdraw approval of an HDE solely because it is subsequently determined that the disease or condition for which the HUD is intended affects or is manifested in more than 4,000 people in the United States per year.

10. Section 814.120 and the heading is revised to read as follows:

§ 814.120 Temporary suspension of approval of an HDE.

An HDE or HDE supplement may be temporarily suspended for the same reasons and in the same manner as prescribed for PMA's in § 814.47.

11. Section 814.124 is amended by adding two sentences at the end of paragraph (a) to read as follows:

§ 814.124 Institutional Review Board requirements.

(a) * * * If, however, a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use. In such an emergency situation, the physician shall, within 5 days after the use of the device, provide written notification to the chairman of the IRB of such use. Such written notification shall include the identification of the patient

involved, the date on which the device was used, and the reason for the use.

12. Section 814.126 is amended by revising the first sentence in paragraph (a) and by revising paragraph (b) to read as follows:

§ 814.126 Postapproval requirements and reports.

(a) An HDE approved under this subpart shall be subject to the postapproval requirements and reports set forth under subpart E of this part, as applicable, with the exception of § 814.82(a)(7). * * *

(b) In addition to the reports identified in paragraph (a) of this section, the holder of an approved HDE shall prepare and submit the following complete, accurate, and timely reports:

(1) *Annual report.* An HDE applicant is required to submit an annual report on the anniversary date of marketing approval. The annual report shall include:

(i) An update of the information required under § 814.102(a) in a separately bound volume;

(ii) An update of the information required under § 814.102(c)(2), (c)(3), and (c)(5);

(iii) The number of devices that have been shipped or sold since initial marketing approval under this subpart H and, if the number shipped or sold exceeds 4,000, an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, the applicant shall submit an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;

(iv) Information describing the applicant's clinical experience with the device since the HDE was initially approved. This information shall include safety information that is known or reasonably should be known to the applicant, medical device reports made under part 803 of this chapter, any data generated from the postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement of contraindications, warnings, precautions, and adverse reactions in the device's labeling; and

(v) A summary of any changes made to the device in accordance with supplements submitted under § 814.108. If information provided in annual reports, or any other information in the possession of FDA, gives the agency reason to believe that a device raises public health concerns or that the criteria for exemption are no longer met, the agency may require the HDE holder to submit additional information to demonstrate continued compliance with the HDE requirements.

(2) *Other.* An HDE holder shall maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing IRB's, as well as any other information requested by a reviewing IRB or FDA.

Dated: March 31, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–9638 Filed 4–16–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–5996–7]

RIN 2060–AE97

National Emission Standards for Hazardous Air Pollutants for Primary Lead Smelters

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rule; notice of public hearing.

SUMMARY: This action proposes national emission standards for hazardous air pollutants (NESHAP) for new and existing primary lead smelters pursuant to section 112 of the Clean Air Act (Act) as amended in November 1990. Primary lead smelters have been identified by the EPA as significant emitters of lead compounds, and other metal hazardous air pollutants (HAP) including arsenic, antimony, and cadmium. Exposure to lead compounds may result in adverse effects on the blood, central nervous system and kidneys. Chronic exposure to arsenic is associated with skin, bladder, liver and lung cancer and other developmental and reproductive effects. This proposed NESHAP provides protection to the public by requiring all primary lead smelters to meet emission standards that reflect the application of maximum achievable control technology (MACT).

DATES: *Comments.* Comments on the proposed rule must be received on or before June 16, 1998.

Public Hearing. If anyone contacts the EPA requesting to speak at a public hearing by May 8, 1998, a public hearing will be held on May 18, 1998, beginning at 10:00 a.m.

ADDRESSES: *Comments.* Written comments should be submitted (in duplicate, if possible) to: Docket No. A–97–33 at the following address: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (6102), 401 M Street, SW., Washington, DC 20460. The EPA requests that a separate copy of the comments also be sent to the contact person listed below.

Electronic comments can be sent directly to EPA's Air and Radiation Docket and Information Center at: ''A-and-R-Docket@epamail.epa.gov.'' Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (A–97–33). No Confidential Business Information (CBI) should be submitted through electronic mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

Docket. Docket No. A–97–33 contains supporting information used in developing the proposed standards. The docket is located at the U. S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460 in room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 12:00 p.m. and 1:00 to 3:00 p.m., Monday through Friday. The proposed regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be mailed on request from the Air Docket by calling (202) 260–7548. A reasonable fee may be charged for copying docket materials.

Public Hearing. If anyone contacts the EPA requesting a public hearing by the required date (see **DATES**), the public hearing will be held at the EPA Office of Administration Auditorium, Research Triangle Park, NC. Persons interested in presenting oral testimony or inquiring as to whether a hearing is to be held should notify the contact person listed below.

FOR FURTHER INFORMATION CONTACT: For information concerning the proposed standards and technical aspects of primary lead smelting emissions and control, contact Mr. Kevin Cavender, Environmental Protection Agency MD–13, Research Triangle Park, NC 27711, telephone number (919) 541–2364, facsimile number (919) 541–5600, electronic mail address ''cavender.kevin@epamail.epa.gov.''.

SUPPLEMENTARY INFORMATION: