neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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. Because this rule only interprets the statute and does not establish any requirements, the agency certifies that this proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Request for Comments

Interested persons may, on or before (*insert date 60 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects in 21 CFR Part 808

Intergovernmental relations, 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 808 be amended as follows:

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

1. The authority citation for 21 CFR part 808 continues to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371.

2. Section 808.1 is amended by adding new paragraphs (d)(11) and (d)(12) to read as follows:

§ 808.1 Scope.

* * * * *

(d) * * *

(11) * * *

(i) An FDA imposed requirement will preempt a State common law duty only when:

(A) FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular device; and

(B) The State common law, as interpreted and applied, imposes a substantive requirement applicable to the same particular device that is different from, or in addition to, FDA's counterpart requirement.

(ii) FDA requirements that are applicable to devices in general, or that are established by means other than through regulation or order, should not result in preemption of State tort claims.

(12) The clearance or approval of a particular device for marketing under section 510(k), 515, or 520(g) of the act does not in itself constitute the imposition of a specific substantive requirement with respect to that particular device that preempts a State or local requirement, including a standard of care imposed under State common law, with respect to the same device.

* * * * *

Dated: December 8, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–32551 Filed 12–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H–371]

RIN 1218–AB46

Occupational Exposure to Tuberculosis

AGENCY: Occupational Safety and Health Administration (OSHA), Labor

ACTION: Proposed rule; extension of comment period; rescheduling of the informal public hearings in Washington D.C.; announcement of additional hearings sites.

SUMMARY: On October 17, 1997, the Occupational Safety and Health Administration (OSHA) published in the **Federal Register** its proposed standard for occupational exposure to tuberculosis (62 FR 54160). An informal public hearing was scheduled for Washington, D.C., and deadlines were set for submission of public comments, Notices of Intention to Appear at the hearing, and documentary evidence from parties requesting more than 10 minutes for their hearing presentations. With this notice, OSHA is extending those deadlines, rescheduling the Washington, D.C., hearings to begin April 7, 1998, and adding three hearing sites.

DATES: Written comments on the proposed standard and Notices of Intention to Appear at the hearings must be postmarked on or before February 13, 1998.

Testimony and documentary evidence from parties requesting more than 10 minutes for their presentations at the hearings must be submitted no later than February 27, 1998.

The hearings will begin April 7, 1998, in Washington, D.C., starting at 10:00 a.m. on the first day and at 9:00 a.m. on succeeding days. Public hearings will also be held in Los Angeles, CA, and Chicago, IL, and New York City, NY. The dates and locations of these additional hearings will be published in the **Federal Register** at a later date.

ADDRESSES: Comments on the proposed standard, Notices of Intention to Appear at the hearings, testimony, and documentary evidence are to be submitted in quadruplicate to the Docket Officer, Docket No. H–371, Room N–2625, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210, telephone (202) 219–7894. Comments of 10 pages or fewer may be transmitted by fax to (202) 219–5046, provided the original and three copies are sent to the Docket Officer thereafter.

All material related to the development of this proposed standard will be available for inspection and copying in the Docket Office Monday through Friday from 10:00 a.m. until 4:00 p.m.

The hearing location for Washington, D.C., is the Frances Perkins Building Auditorium, U.S. Department of Labor, 200 Constitution Avenue, NW. The hearing locations and dates for Los Angeles, CA, and Chicago, IL and New

York City, NY will be announced at a later date.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Room N–3647, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210, Telephone (202) 219–8148, FAX (202) 219–5986.

SUPPLEMENTARY INFORMATION: OSHA proposed a new standard for occupational exposure to tuberculosis on October 17, 1997 (62 FR 54160). The deadline for submitting written comments was December 16, 1997. On November 5, 1997, five organizations representing more than 4 million individuals and 5,300 facilities potentially affected by the proposed standard, collectively requested that OSHA consider extending the public comment period by a minimum of 30 days. Citing the complexity and the far-reaching implications of the proposed standard, these organizations stated that they believed that the current deadline of December 16, 1997, provided insufficient time for a thorough examination and consideration of the important issues. A similar request was made by the American Medical Association, which urged OSHA to extend the deadline to allow sufficient time for a complete and thoughtful analysis of the proposed TB standard.

OSHA considers the testimony to be offered by these organizations to be important and necessary for the development of the final rule. In addition, OSHA recognizes that other parties that will be affected by the rulemaking may need more time to prepare their comments and testimony. In order to accommodate these organizations and others, OSHA has extended the comment period and has rescheduled the informal public hearings in Washington, D.C.

The deadline for written comments and Notices of Intention to Appear at the informal public hearings is being extended from December 16, 1997, to February 13, 1998. The deadline for submission of testimony for parties requesting more than 10 minutes at the public hearings or submitting documentary evidence is being extended from December 31, 1997, to February 27, 1998. The hearing presently scheduled to begin on February 3, 1998 in Washington, D.C., is being rescheduled to begin on April 7, 1998.

In addition to the informal public hearings in Washington D.C., three sites are being added: Chicago, IL, and Los Angeles, CA, and New York City, NY. Because the proposed standard will impact employees and employers across the nation, the Agency believes that is appropriate to hold public hearings at additional sites in order to give parties who may not be able to attend the hearings in Washington, D.C., an opportunity to participate in the public hearing process. OSHA has found that the hearings provide an important forum for interested parties to submit their comments and concerns on OSHA's proposed rulemakings and that the hearings provide the Agency with valuable information in developing its final standards.

Public Participation

Persons desiring to participate at the hearings must submit four copies of a Notice of Intention to Appear containing the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The hearing site that the party is requesting to attend;

(3) The capacity in which the person will appear;

(4) The approximate amount of time requested for the presentation;

(5) The specific issues that will be addressed;

(6) A detailed statement of the position that will be taken with respect to each issue addressed;

(7) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence; and

(8) Whether the party wishes to testify on the days set aside to focus on homeless shelters.

A tentative schedule of appearances at the hearings will be prepared and distributed to parties who have submitted Notices of Intention to Appear so parties will know when issues that concern them are likely to be raised at the hearing.

Filing of Testimony and Evidence Before Hearings

Any party requesting more than 10 minutes for a presentation at the hearing, or who will present documentary evidence, must submit four copies of the complete text of the testimony, including any documentary evidence to be presented at the hearing to the Docket Officer at the above address.

Each submission will be reviewed in light of the amount of time requested in the Notice of Intention to Appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation. Any party who has not filed a Notice of Intention to Appear may be allowed to testify, as time permits, at the discretion of the Administrative Law Judge.

OSHA emphasizes that the hearing is open to the public, and that interested persons are welcome to attend. However, only persons who have filed Notices of Intention to Appear will be entitled to ask questions and otherwise participate fully in the proceeding.

Authority

This document has been prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210.

It is issued under section 6(b) of the Occupational Safety Health Act (29 U.S.C. 655), Secretary of Labor's Order 6–96, (62 FR 111) and 29 CFR Part 1911.

Signed at Washington, D.C. on this 9th day of December, 1997.

Charles N. Jeffress,

Assistant Secretary of Labor.

[FR Doc. 97–32546 Filed 12–9–97; 3:59 pm]

BILLING CODE 4510–26–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[CC Docket No. 96–45 and 97–160; DA 97–2372]

Universal Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; guidance for design and submission of proposed models.

SUMMARY: The Common Carrier Bureau (Bureau) provided guidance to proponents of forward-looking cost models in the universal service proceeding on issues related to customer location and outside plant design. The Bureau provided this guidance to improve the models that the Commission will consider to select a mechanism for determining non-rural carriers' forward-looking cost to provide the supported services. This guidance is intended to encourage model proponents to alter their models to conform them to the guidance provided in this Public Notice. Models conforming to the guidance provided in this Public Notice are more likely to be considered favorably in this proceeding.