Paragraph 6009(c)—Amber Federal Airways

A–1 [Revised]

From Sandspit, BC, Canada, NDB 96 miles 12 AGL, 102 miles 35 MSL, 57 miles 12 AGL, via Sitka, AK, NDB; 31 miles 12 AGL, 50 miles 47 MSL, 88 miles 20 MSL, 40 miles 12 AGL, Ocean Cape, AK, NDB; INT Ocean Cape NDB 283° and Hinchinbrook, AK, NDB 106° bearings; Hinchinbrook NDB; INT Hinchinbrook NDB 286° and Campbell Lake, AK, NDB 123° bearings; Campbell Lake NDB; Takotna River, AK, NDB; 24 miles 12 AGL, 53 miles 55 MSL; 51 miles 40 MSL, 25 miles 12 AGL, North River, AK, NDB; 17 miles 12 AGL, 89 miles 25 MSL, 17 miles 12 AGL, to Fort Davis, AK, NDB. That airspace within Canada is excluded.

* * * * *

Issued in Washington, DC, on December 2, 1997.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 97–32569 Filed 12–11–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 960

[Docket No. 951031259–7103–02]

Licensing of Private Land Remote-Sensing Space Systems

AGENCY: National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice; extension of public comment period.

SUMMARY: Pursuant to public request, the National Oceanic and Atmospheric Administration (NOAA) is extending by 90 days its public comment period for the Notice of Proposed Rulemaking concerning the licensing of private land remote-sensing space systems, published on November 3, 1997, 62 FR 59317.

DATES: Comments must be received by April 2, 1998.

ADDRESSES: Comments should be sent to, Charles Wooldridge, NOAA, National Environmental Satellite, Data, and Information Service, 1315 East-West Highway Room 3620 Silver Spring, MD 20910–3282.

FOR FURTHER INFORMATION CONTACT: Charles Wooldridge at (301) 713–2024 ext. 107 or Kira Alvarez, NOAA, Office of General Counsel at (301) 713–1217.

SUPPLEMENTARY INFORMATION: On November 3, 1997, NOAA published a Notice of Proposed Rulemaking (62 FR 59317) proposing regulations revising its regime for the licensing of private Earth remote-sensing space systems under Title II of the Land Remote Sensing Policy Act of 1992, 15 U.S.C. 5601 *et seq.* (1992 Act). These proposed regulations implement the licensing provisions of the 1992 Act and the Presidential Policy announced March 10, 1994. In response to numerous written comments, NOAA is extending the original 60 day public comment period by 90 days. As a result, comments on the notice of proposed rulemaking must now be received by April 2, 1998.

Dated: December 5, 1997.

Gregory W. Withee,

Deputy Assistant Administrator for Satellite and Information Services.

[FR Doc. 97–32472 Filed 12–11–97; 8:45 am]

BILLING CODE 3510–12–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 808

[Docket No. 97N–0222]

Medical Devices; Preemption of State Product Liability Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding preemption of State and local requirements applicable to medical devices. This action is being taken to clarify and codify the agency's longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments by February 10, 1998.

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

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 521 of the act (21 U.S.C. 360k) contains an express preemption provision applicable to medical devices regulated by FDA. The Supreme Court recently addressed whether section 521 of the act preempts State common law tort claims arising from allegedly defective medical devices. (See *Medtronic, Inc.* v. *Lohr (Lohr)*, 116 S. Ct. 2240 (1996).) The Court concluded that section 521 of the act did not supplant the State law duties at issue in that case. In reaching that conclusion, the Court noted that FDA has provided interpretive guidance with respect to section 521 of the act's preemptive effect. (See *id.* at 2255–2256 (citing 21 CFR 808.1(d)(2) and 808.5(b)(1)(i) (1995)).) The Court gave ''substantial weight to the agency's view of the statute'' (*Id.* at 2256). (See also *id.* at 2257; *id.* at 2260–2261 (Breyer, J., concurring in part and concurring in the judgment).)

The Court's decision in *Lohr* construed section 521 of the act in the context of a medical device that FDA had cleared for distribution under section 510(k) of the act (21 U.S.C. 360k), which requires premarket notification for certain types of medical devices. The Court did not definitively decide whether section 521 of the act may preempt State law claims in other circumstances. Since *Lohr* was decided, the lower courts have interpreted section 521 of the act inconsistently and have reached conflicting conclusions with respect to whether section 521 of the act preempts State law claims for injuries allegedly resulting from medical devices that have received premarket approval under section 515 of the act (21 U.S.C. 360e), or have received an investigational device exemption (IDE) under section 520(g) of the act (21 U.S.C. 360j(g)).

In light of the confusion among the lower courts in interpreting section 521 of the act since *Lohr*, and in accordance with the Supreme Court's recognition that FDA's interpretation of the preemptive effect of section 521 is entitled to substantial weight, the agency is issuing this proposed interpretive rule, which addresses the circumstances in which section 521 of the act preempts State common tort claims based on injury from allegedly defective medical devices.

II. Background

Congress enacted the Medical Device Amendments of 1976 (the amendments) (21 U.S.C. 360c *et seq.*), ''to provide for the safety and effectiveness of medical devices intended for human use.'' It

enacted the amendments largely in response to public concerns over injuries caused by medical products, such as the Dalkon Shield intrauterine device. (See S. Rept. No. 33, 94th Cong., 1st sess. 1 (1975); H. R. Rept. No. 853, 94th Cong., 2d sess. 8 (1976); 122 Congressional Record 13,779 (1976)). Congress sought ''to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions'' (H. R. Rept. No. 853, *supra*, at 12).

Section 521 of the act was included as part of the amendments, and generally states that except as provided in section 521(b) of the act no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any Federal requirement applicable to the device, and which relates to the safety or effectiveness of the device or to any other matter included in a Federal requirement applicable to the device.

Section 521(b) sets forth the requirements if a political subdivision thereof applies for an exemption from a Federal requirement. The Secretary may issue a regulation to exempt from section 521(a) of the act, under conditions prescribed in the regulation, if the requirement is more stringent than the Federal requirement which would be applicable to the device if an exemption were not in effect or the requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable Federal requirement under this chapter.

FDA has interpreted the preemptive scope of section 521 of the act in light of its specific language and Congress's expressed objectives. Section 521(a) forbids a State from subjecting a medical device to any ''requirement'' that is ''different from, or in addition to,'' any Federal requirement imposed under the act; and relates to ''the safety or effectiveness of the device'' or to ''any other matter'' included in the Federal requirement. FDA has indicated, through regulations that have been in place since 1978, that section 521 of the act's preemptive effect is limited in light of the section's precise terminology and Congress's declared intention to promote the safety and effectiveness of medical devices. (See 21 CFR 808.1.)

When FDA issued its 1978 regulations, the regulated community was primarily interested in the effect of section 521 of the act on State or local requirements that were expressed through positive enactments, such as statutes or regulations. FDA's regulations addressed the question of preemption in that general context. Section 808.1(d), which has remained substantially unchanged for nearly 20 years, states that State or local requirements are preempted only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific FDA requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not ''requirements applicable to a device'' within the meaning of section 521(a) of the act.

FDA's regulations (§ 808.1) provide nine examples of State or local provisions that are not preempted, including:

(1) Generally applicable requirements not limited to medical devices (e.g., general electrical codes and the Uniform Commercial Code (warranty of fitness));

(2) Requirements that are equal to or substantially identical to requirements imposed by or under the act;

(3) Occupational licensing requirements;

(4) Specifications in government contracts for the procurement of devices;

(5) Criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health care programs;

(6) General enforcement requirements, including State inspection and registration requirements, or a State or local prohibition against the manufacturer of adulterated or misbranded devices (except where the prohibition, as interpreted and enforced, has the effect of establishing a substantive requirement for a specific device);

(7) Provisions respecting delegations of authority and related administrative matters respecting devices;

(8) Fee and other revenue raising requirements; and

(9) State or local requirements issued under the authority of other Federal statutes.

In 1992, the Supreme Court decided *Cippolone* v. *Liggett Group, Inc.* (505 U.S. 504 (1992)). Among other things, the Court ruled in that case that section 5(b) of the Public Health Cigarette Smoking Act of 1969 (15 U.S.C. 1334(b)) could preempt State common law suits alleging that the manufacturers breached their duty to warn about hazards associated with smoking. Section 5(b) states that no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

A majority of the Supreme Court concluded that the phrase ''[n]o requirement or prohibition,'' as used in that statute, describes both positive enactments and common law duties. (See 505 U.S. at 521 (opinion of Stevens, J.); *id.* at 548–549 (Scalia, J., concurring in the judgment in part and dissenting in part).)

After the Supreme Court's decision in *Cippolone*, a number of lower courts interpreted section 521 of the act to preempt tort actions respecting allegedly defective medical devices in which the plaintiff sought to hold the manufacturer liable based on State common law. Those courts found preemption in a variety of contexts, including situations in which FDA had allowed marketing of the device after ''premarket notification'' under section 510(k) of the act (21 U.S.C. 360(k)), (e.g., *Mendes* v. *Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994)); in which FDA had granted premarket approval of the device under section 515 of the act (21 U.S.C. 360e), (e.g., *King* v. *Collagen Corp.*, 983 F.2d 1130 (1st Cir.) *cert. denied*, 510 U.S. 824 (1993)); and in which FDA had granted an IDE under section 520(g) of the act (21 U.S.C. 360j(g)), (e.g., *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992)).

The Supreme Court addressed the scope of section 521 of the act's preemptive effect in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996). That case arose out of Medtronic's marketing of a cardiac pacemaker that FDA found was ''substantially equivalent'' to a medical device already on the market and that was therefore subject to the premarket notification requirements of section 510(k) of the act (21 U.S.C. 360(k)). The plaintiffs alleged that they were injured by the device and sought damages under Florida common law. They asserted that Medtronic breached its common law duty ''to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker'' and that Medtronic was strictly liable because the device ''was in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale'' (116 S. Ct. at 2248).

The Court concluded that section 521 of the act did not preempt the plaintiffs' negligent design claim. It specifically rejected Medtronic's contention that the company's compliance with its statutory obligation to demonstrate through the premarket notification process that the pacemaker was ''substantially equivalent'' to a preexisting device preempted those claims (116 S. Ct. at 2254–2255). The Court noted that, when FDA reviews a device under the premarket notification provisions, it does so with ''a concern for the safety and effectiveness of the device'' (*id*. at 2254), but that FDA ''did not 'require' Medtronics' pacemaker to take any particular form for any particular reason'' (*ibid*). Rather, FDA simply allowed Medtronic to market the pacemaker based on the article's equivalence to the preexisting device (*Id*. at 2254–2255). The Supreme Court was unanimous on this point, since Justice O'Connor's separate opinion for four Justices agreed that the section 510(k) premarket notification process ''places no 'requirement' on a device'' and therefore does not preempt a defective design claim (*Id*. at 2264).

The Court also concluded that section 521 of the act did not preempt the plaintiffs' State law claims that Medtronic had violated FDA requirements (116 S. Ct. at 2255–2256). The Court reasoned that State common law claims premised on Medtronic's failure to comply with FDA requirements do not subject the manufacturer to requirements that are ''different from, or in addition to,'' the Federal requirements (*Id*. at 2255). The Court noted that FDA's interpretive regulations ''expressly support the conclusion that [section 521] 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.''' (*Id*. at 2256 (quoting 21 CFR 808.1(d)(2) (1995))). It also observed that FDA's views on the scope of section 521 of the act's preemptive effect are entitled to ''substantial weight.'' (*Ibid*).

The Court additionally concluded that section 521 of the act did not preempt the plaintiffs' State law claims based on negligent manufacturing and labeling (116 S. Ct. at 2256–2258). The Court recognized that FDA had developed regulations that set out general ''requirements'' for manufacturing and labeling medical devices (*Id*. at 2256). It concluded, however, that section 521 generally does not mandate preemption of a standard of care under State common law unless, as FDA had suggested in its interpretive regulations, FDA has issued ''specific counterpart regulations or * * * other specific requirements applicable to a particular device'' (*Id*. at 2257 (quoting 21 CFR 808.1(d) (1995))). The Court concluded that the ''entirely generic'' Federal requirements did not provide a basis for preemption of the nonspecific State common law duties at issue in that case (*Id*. at 2258). Justice Breyer, agreeing with Justice O'Connor's opinion (see *id*. at 2262–2263), concluded that, insofar as the act preempts a State requirement embodied in a statute or regulation, it also preempts a similar State requirement that takes the form of a standard of care imposed by State tort law (*id*. at 2259–2260), but he concurred in the Court's holding that manufacturing and labeling requirements issued by FDA were not sufficiently specific to trigger preemption (*id*. at 2260–2261).

Since the Supreme Court's decision in *Lohr*, the lower courts have continued to reach contradictory determinations respecting section 521 of the act's preemptive effect, particularly as it relates to medical devices that have received premarket approval or an investigatory device exemption. Compare, e.g., *Fry* v. *Allergan Medical Optics*, 695 A.2d 511 (R.I. 1997) (finding preemption), *cert. denied*, No. 97–513 (U.S. Sup. Ct., Nov. 3, 1997) with *Kernats* v. *Smiths Indus. Med. Sys., Inc.*, 669 N.E. 2d 1300 (Ill. App. Ct.) (finding no preemption), *appeal denied*, 675 N.E.2d (Ill. 1996), *petition for cert. pending*, No. 96–1405 (U.S. Sup. Ct., filed Mar. 4. 1997).

III. The Proposed Rule

FDA interprets section 521 of the act's preemptive effect on the basis of congressional intent. As the Supreme Court stated in *Lohr*, congressional purpose ''is the ultimate touchstone'' in every preemption case, and ''a fair understanding of congressional purpose'' may be discerned not only from the text of the statute, but also through a ''reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law'' (116 S. Ct. at 2250–2251 (emphasis deleted)). In addition, the statutory text must be read in light of established presumptions respecting preemption. As the Supreme Court stated in *Lohr*, the States are presumed to retain their historic police powers unless Congress expresses a ''clear and manifest purpose'' to supersede those powers (*Id*. at 2250).

Section 521 of the act does not, as a general matter, prevent a party who is injured by a defective medical device from seeking redress under a State's common law. Rather, section 521(a) of the act provides that a State may not ''establish or continue in effect with respect to a device'' a ''requirement'' that is ''different from, or in addition to,'' a ''requirement applicable under this chapter to the device'' that ''relates to the safety or effectiveness of the device'' or to ''any other matter included in'' the Federal requirement (21 U.S.C. 360k(a)). By its plain terms, section 521 of the act does not prevent a State from imposing common law duties on manufacturers of medical devices unless those duties are ''requirements'' of the kind described in the statute.

When FDA articulated its understanding of section 521 of the act in its 1978 regulations, it stated the general rule to be that ''State or local requirements are preempted only when the agency has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements'' (§ 808.1(d)). The Supreme Court explicitly endorsed FDA's position in the *Lohr* decision. (See 116 S. Ct. at 2257; *id*. at 2260–2261 (Breyer, J., concurring in part and concurring in the judgment)). Similarly, the 1978 regulations provide that section 521 of the act does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices, but that where such a prohibition, as ''interpreted and enforced by the State and local government,'' ''has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement,'' it will be preempted if it is different from, or in addition to, a specific requirement established by FDA for the device (§ 808.1(d)(6)(ii)).

In 1978, FDA stated its understanding of section 521 of the act in the general context of State requirements that are imposed through positive law, such as statutes or regulations. The same principles should govern, however, in the case of State requirements that are imposed through the common law. FDA has consistently concluded that the same principles govern when it has addressed the question of preemption through its regulations, advisory opinions, and its judicial filings as amicus curiae. The Supreme Court implicitly endorsed that conclusion in the *Lohr* decision by applying the principles that FDA has announced in its 1978 regulations to the Lohrs'

common law suit. (See 116 S. Ct. at 2255–2256, 2257–2258; *id.* at 2260–2261 (Breyer, J., concurring in part and concurring in the judgment in part)).

In accordance with the principles that FDA articulated in its 1978 regulations, to which the Supreme Court in *Lohr* held that deference is owed, FDA believes that, as a general matter, an FDA-imposed requirement will preempt a State common law duty only when: (1) FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular medical device; and (2) the State common law, as interpreted and applied, imposes a substantive requirement applicable to the same particular medical device that is different from, or in addition to, FDA's counterpart requirement. Under this approach, FDA requirements that are applicable to devices in general, or that are established by means other than through regulation or order, should generally not result in preemption of State tort claims.

FDA bases its interpretation primarily on the language of section 521 of the act and the agency's past regulatory interpretation set out in § 808.1. In addition, a plurality of the Court noted in *Lohr* that there is no indication in the legislative history of the amendments that Congress intended to make a ''dramatic change'' in the availability of State common law remedies (*Id.* at 2253 n.13 (opinion of Stevens, J.)). The legislative history indicates that Congress was aware of ongoing product liability suits involving medical devices, but it contains no indication that Congress intended that the amendments would preempt those suits. See, e.g., S. Rept. No. 33, supra, at 1; H. R. Rept. No. 853, *supra*, at 8; 121 Congressional Record 10,688 (1975) (Sen. Kennedy); *id.* at 10,689 (Sen. Nelson); 122 Congressional Record 5850 (1976) (Rep. Abzug)).

FDA's interpretation is also founded in its experience and understanding gained through implementing the amendments. FDA believes that its general regulatory review and approval processes provide a significant measure of protection against the marketing of dangerous or defective medical devices. FDA does not believe, however, that those processes can guarantee the safety of such devices. Accordingly, compliance with general FDA requirements should not broadly preempt State common law remedies, which provide an important (and frequently the only) mechanism for persons to seek redress for injuries resulting from defective medical devices. FDA notes below several situations in which the agency's regulatory activities will typically not preempt State law remedies.

First, FDA's general clearance and approval processes, such as the clearance for marketing under section 510(k) of the act; the grant premarket approval under section 515 of the act; or the grant of an IDE under section 520(g) of the act, do not, by themselves, preempt State common law claims. Section 521 of the act provides for preemption of a State common law duty only if it imposes a requirement that is different from, or in addition to, a specific substantive requirement pertaining to the particular device that has been imposed by or under the act. FDA's action in clearing a product for marketing or granting an application for a PMA or an IDE signifies that the manufacturer's proposal for marketing or use of the device in question satisfies the relevant statutory and regulatory criteria for the clearance, approval, or exemption. It does not signify, however, that Congress or FDA has established a specific Federal requirement (e.g., with respect to the design of the device) that supplants a State common law duty.

Second, FDA's notification of deficiencies in, or proposal of modifications to, an application for a PMA or an IDE does not, as a general matter, create specific Federal requirements that have preemptive effect. Under FDA's approval and exemption programs, the applicant bears responsibility for preparing an acceptable application. FDA may notify the applicant of deficiencies and propose modifications to ensure that the applicant has satisfied the minimum standards for FDA approval or exemption, but those actions do not relieve the applicant of its ultimate responsibility for proposing the design, manufacturing, and labeling of the device. For purposes of preemption analysis, the applicant who modifies an application in response to an agency notification of deficiency or proposal for modification has simply achieved the same status as an applicant who had submitted a satisfactory application at the outset.

Third, as the Supreme Court concluded in *Lohr*, FDA's general requirements respecting labeling (21 CFR 801.1 through 801.16), and good manufacturing practices, (21 CFR 820.1 through 820.198), do not preempt State requirements, because the general Federal requirements do not pertain to specific devices. (See *Lohr*, 116 S. Ct. at 2256–2258). The same controlling principle applies whether the device subject to those requirements is a ''grandfathered'' device that was marketed before the enactment of the amendments, received FDA clearance for marketing under section 510(k) of the act, received a PMA under section 515 of the act, or received an IDE under section 520(g) of the act.

Fourth, even if FDA has imposed specific Federal requirements respecting a particular medical device, those requirements do not preempt all State common law claims respecting the device. Section 521 of the act provides for preemption only if the State common law duties are ''different from, or in addition to,'' the specific Federal requirements. In many cases, preemption will depend on the plaintiff's precise legal claims and theories of recovery. For example, as the Supreme Court noted in *Lohr*, if the state common law required the manufacturer to comply with the Federal requirements, section 521 of the act would not preempt that duty (116 S. Ct. at 2255–2256). Furthermore, the courts may be able to reconcile an apparent conflict between Federal and State requirements by, for example, carefully formulating jury instructions to limit the bases for liability to substantive standards of care that are consistent with any specific requirement that FDA has made applicable to the device.

In every case, section 521 of the act's preemptive effect should be evaluated in light of the statute's precise terms. As the Supreme Court noted in *Lohr*, section 521 of the act and FDA's regulations ''require a careful comparison between the allegedly preempting Federal requirement and the allegedly preempted State requirement to determine whether they fall within the intended preemptive scope of the statute and regulations'' (116 S. Ct. at 2257–2258). The outcome of particular cases will frequently depend on the character and circumstances of the particular state law claim. FDA will continue to monitor the development of the law in this area and provide additional guidance as the need arises.

This proposed rule would make no change in the agency's prior or current construction of the scope of section 521 of the act. Rather, the rule would simply clarify and codify the agency's longstanding interpretation of the scope of section 521 of the act as generally not preempting available legal remedies, including State common law tort claims.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

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