case, each foreign board of trade whose products would be made available through U.S.-located computer terminals would be required to comply with any requirements adopted by the Commission in its order. For example, if two or more foreign boards of trade share the same computer terminal platform and each wished to place computer terminals in the U.S. for the use of its members (or members' affiliates), each would be required to receive an order from the Commission and comply with the requirements in that order under the approach described above. The Division's approach would also arguably apply to a foreign board of trade which trades through terminals shared with a U.S. exchange that has been designated as a U.S. contract market.[50] The Commission requests comment as to whether different requirements should apply to a foreign board of trade's products which are traded on the computer terminals of a U.S. contract market. If so, how should such requirements differ and why?

III. Conclusion

The Commission believes that it is appropriate to develop rules concerning placement of foreign board of trade terminals in the U.S. in light of the growing interest among foreign boards of trade to do so. The Commission hopes to develop an approach to address these issues that will provide certainty to foreign exchanges that wish to place their computer terminals in the U.S. for trading purposes and will be consistent with the Commission's obligations under the Act to maintain the integrity and competitiveness of the U.S. markets and to provide protection to U.S. customers. To this end, the Commission requests public comment on the issues and the Division's approach, as discussed above.

Issued in Washington, D.C. on July 17, 1998 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 98–19723 Filed 7–23–98; 8:45 am]

BILLING CODE 6351–01–M

[50] The Commission anticipates that a foreign board of trade that currently is trading its products through computer terminals in the U.S. would be required to comply with any new rules eventually adopted by the Commission, but would be provided a transition period in which to come into compliance.

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: Withdrawal of proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is withdrawing a proposed rule that published in the **Federal Register** of December 12, 1997 (62 FR 65384), relating to medical device preemption of State product liability claims. FDA is making this withdrawal because of concerns that have been raised regarding the interplay between the FDA Modernization Act of 1997 (FDAMA) and the proposed rule.

DATES: The proposed rule is withdrawn July 24, 1998.

ADDRESSES: Copies of the draft proposed rule and its comments may be obtained from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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: Section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k) contains an express preemption provision applicable to medical devices regulated by FDA. The Supreme Court 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 for devices marketed pursuant to a premarket clearance issued under section 510(k) of the act (21 U.S.C. 360(k)). 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 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 of the act is entitled to substantial weight, the agency issued the proposed rule in the **Federal Register** of December 12, 1997 (62 FR 65384), addressing the circumstances under which section 521 of the act preempts State common law tort claims based on injury from allegedly defective medical devices. The proposal is consistent with the position that the agency has historically taken on issues related to device preemption. The comment period on this proposed rule was open until February 10, 1998. The agency received 41 comments from a variety of associations, law firms, and individuals representing industry and consumer interests.

FDA has decided to withdraw the rulemaking to amend its regulations regarding preemption of State and local requirements applicable to medical devices. FDA is taking this action because, even though the proposed rule was issued after the enactment of FDAMA, it was conceptualized and written prior to enactment.

Concerns have been raised by industry and congressional representatives that the agency did not share its thinking on its interpretation of section 521 of the act during FDAMA deliberations, even though an early draft of the proposed rule was shared during the spring of 1997 with attorneys for Public Citizen Litigation Group, who represented Lohr in the *Lohr* case. The remedy under FDA's regulations for disclosure of a draft regulation is ordinarily to issue a notice in the **Federal Register** making the draft publicly available. See 21 CFR 10.80(b)(2). Such a contemporaneous notice was not, however, provided in this case.

Because of the great policy significance of these preemption issues, the concern that Congress was not aware of the agency's thinking during FDAMA deliberations, and the potential interplay between the FDAMA device provisions and device preemption, the agency believes that it is imperative for all interested parties to have confidence that the agency is addressing their concerns in an impartial manner. Therefore, the agency is taking the unusual step of withdrawing the proposed rule.

The early draft of the proposed rule that was disclosed, the comments on it, and the correspondence raising

concerns about the disclosure are being placed in the Dockets Management Branch (address above) and can be identified with the docket number found in brackets in the heading of the document.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19916 Filed 7–21–98; 5:07 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[WV–077–FOR]

West Virginia Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening of public comment period and opportunity for a public hearing.

SUMMARY: OSM is reopening the public comment period on certain parts of a proposed amendment to the West Virginia permanent regulatory program (hereinafter referred to as the West Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment was submitted on April 28, 1997 (with revisions submitted on May 14, 1997) and amends both the West Virginia Surface Mining Reclamation Regulations and the West Virginia Surface Mining Code. The comment period is being reopened specifically on the amendments to the definition of surface mining, special authorizations, fish and wildlife as a postmining land use for mountaintop removal operations, removal of abandoned coal refuse piles, remining, and no-cost reclamation. The amendments are intended to revise the State program to be consistent with the counterpart Federal provisions and to improve the effectiveness of the West Virginia program.

DATES: Written comments must be received on or before 4:00 p.m. on August 24, 1998. If requested, a public hearing on the proposed amendments will be held at 1:00 p.m. on August 18, 1998. Requests to present oral testimony at the hearing must be received on or before 4:00 p.m. on August 10, 1998.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to Mr. Roger W. Calhoun, Director, Charleston Field Office at the address listed below.

Copies of the West Virginia program, the program amendments, and the administrative record on the West Virginia program are available for public review and copying at the addresses below, during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed changes by contacting the OSM Charleston Field Office.

Mr. Roger W. Calhoun, Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301 Telephone: (304) 347–7158.

West Virginia Division of Environmental Protection, 10 McJunkin Road, Nitro, West Virginia 25143, Telephone: (304) 759–0515

In addition, copies of the amendments that are the subject of this notice are available for inspection during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Morgantown Area Office, 75 High Street, Room 229, P.O. Box 886, Morgantown, West Virginia 26507, Telephone: (304) 291–4004

Office of Surface Mining Reclamation and Enforcement, Beckley Area Office, 323 Harper Park Drive, Suite 3, Beckley, West Virginia 25801, Telephone: (304) 255–5265

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Charleston Field Office; Telephone: (304) 347–7158.

SUPPLEMENTARY INFORMATION:

I. Background on the West Virginia Program

On January 21, 1981, the Secretary of the Interior conditionally approved the West Virginia program. Background information on the West Virginia program, including the Secretary's findings, the disposition of comments, and the conditions of the approval can be found in the January 21, 1981, **Federal Register** (46 FR 5915–5956). Subsequent actions concerning the West Virginia program and previous amendments are codified at 30 CFR 948.10, 948.12, 948.13, 048.15, and 948.16.

II. Discussion of the Proposed Amendment

By letter dated April 28, 1997 (Administrative Record Number WV–1056), the West Virginia Division of Environmental Protection (WVDEP) submitted an amendment to its approved permanent regulatory program pursuant to 30 CFR 732.17. Some revisions of the original amendments were submitted by letter dated May 14, 1997 (Administrative Record Number WV–1057). The amendment revises the West Virginia Surface Mining Reclamation Regulations (CSR Section 38–2 *et seq.*), and Sec. 22–3 of the West Virginia Surface Mining Code. The amendment concerns changes to implement the standards of the Federal Energy Policy Act of 1992, and other changes desired by the State.

During OSM's review of the proposed amendments the State submitted a new amendment to its Surface Mining Reclamation Regulations at CSR 38–2 by letter dated may 11, 1998 (Administrative Record Number WV 1086). The public comment period on the new amendment is open until July 15, 1998 (63 FR 32632; June 15, 1998). Certain of the proposed regulations in the new amendment are intended to implement some of the statutes which OSM is reviewing under the current amendment. Therefore, OSM is reopening the public comment period on the specific statutes identified below for which the State has recently submitted a new amendment containing implementing regulations. In addition, OSM received a request from a commenter that the public comment period be reopened on the proposed amendments at Section 22–3–13(c)(3) concerning the proposed addition of fish and wildlife habitat and recreation lands as an approvable postmining land use for mountaintop removal operations.

The Director is reopening the public comment period on the following Sections:

22–3–3(u) concerning the definition of ''surface mine,'' ''surface mining'' or ''surface mining operations;''

22–3–3(y) concerning the definition of ''lands eligible for remining;''

22–3–13(b)(20) concerning the revegetation responsibility period for lands eligible for remining;

22–3–13(c) concerning the proposed addition of fish and wildlife habitat and recreation lands as an approvable postmining land use for mountaintop removal operations; and

22–3–28 concerning special authorization for reclamation of existing abandoned coal processing waste piles; coal extraction pursuant to a government financed reclamation contract; coal extraction as an incidental part of development of land for commercial, residential, industrial, or civic uses; and no cost reclamation contracts.