substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL MI E5 Cadillac, MI [Revised]

(lat. 44°16′31″ N., long. 85°25′08″ W.)

That airspace extending upward from 700 feet above the surface within a 7.4 mile radius of the Wexford County Airport and within 3.9 miles either side of the 246 degree bearing from the airport extending from the 7.4 mile radius to 8.3 miles southwest of the airport, and within 1.7 miles either side of the 062 degree bearing from the airport extending from the 7.4 mile radius to 10.3 miles northeast of the airport.

* * * * *

Issued in Des Plaines, Illinois on May 22, 1995.

Roger Wall,

Manager, Air Traffic Division.

[FR Doc. 95–13939 Filed 6–6–95; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Part 792

[Docket No. 950525141–5141–01]

Administration of State Log Exports Ban

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Advance notice of proposed rulemaking with request for comments.

SUMMARY: This notice announces the Department of Commerce's intention to issue regulations implementing the ban on the export of unprocessed timber originating from non-Federal public lands in 17 western states pursuant to the Forest Resources Conservation and Shortage Relief Act of 1990, as amended (FRCSRA). This notice delineates the actions the Department is considering taking to implement the FRCSRA and requests public comments on these actions.

DATES: Comments must be received by July 7, 1995.

ADDRESSES: Written comments (three copies) should be sent to: Steven C. Goldman, Acting Director, Office of Chemical and Biological Controls and Treaty Compliance, Bureau of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230, Telephone: (202) 482–3825, Fax (202) 482–0751.

FOR FURTHER INFORMATION CONTACT: Bernard Kritzer, Manager, Short Supply Program, Office of Chemical and Biological Controls and Treaty Compliance, Bureau of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230, Telephone: (202) 482–0894, Fax (202) 482–0751.

SUPPLEMENTARY INFORMATION:

Background

Section 491 of the Forest Resources Conservation and Shortage Relief Act of 1990, (Pub. L. 101–382, 16 U.S.C. 620 et seq.) (the Act), requires the Secretary of Commerce to issue orders restricting the export of unprocessed timber originating from non-Federal public lands located west of the 100th meridian in the contiguous United States (state timber). Prior to its amendment in 1993, the Act required the affected States to issue and implement regulations administering the export ban. On May 4, 1993, the U.S. Ninth Circuit Court of Appeals held unconstitutional the provisions of the Act that required the States to implement the Act's prohibitions.

On July 1, 1993, the President signed into law Public Law 103–45, the Forest Resources Conservation and Shortage Relief Amendments Act of 1993 (the Amendments Act). The Amendments Act reassigned the export control implementation responsibilities from the States to the Federal government (Federal Program), specifically to the Secretary of Commerce. It also allows individual states to petition the Secretary to approve their own programs to implement the ban on exports of state timber (State Program). If the Secretary approves a State Program, it applies in that State in lieu of the Federal Program.

Scope of the Export Ban

Pursuant to the FRCSRA, on August 23, 1993, the Secretary of Commerce signed a General Order (Order) prohibiting the export of State timber effective June 1, 1993 (58 F.R. 55038). This Order affects Arizona, California, Colorado, Idaho, Kansas, Montana, Nebraska, New Mexico, Nevada, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming (the affected States). The export ban, however, excludes public lands in the State of Alaska and lands held in trust by any Federal or State official or agency for a recognized Indian tribe or for any member of such tribe.

The Order includes restrictions on who may purchase state timber to prevent the direct or indirect substitution of such timber for exported private timber. It also provides exemptions for certain prior contracts. For States with annual sales greater than 400 million board feet (MBF), the Order expires December 31, 1995. For States with annual sales of less than 400 MBF, the Order remains in effect permanently.

For States with annual sales of more than 400 MBF, section 491 (b)(2)(B) of the FRCSRA requires the Secretary to issue an Order, not later than September 30, 1995, for all periods on or after January 1, 1996, prohibiting the export of the lesser of 400 MBF or the annual sales volume in that State of unprocessed timber originating from public lands.

The FRCSRA allows the governor of each affected State to request that the Secretary of Commerce approve a State Program for the administration of its own state timber export controls in lieu of the Federal Program. On August 17, 1993, the Secretary authorized Washington to continue administering its pre-existing export control program on an interim basis. On March 10, 1994, the Secretary authorized Oregon to continue administering its pre-existing export control program on an interim basis. On June 1, 1995, the Secretary gave final authorization to Oregon and Washington to administer their pre-existing programs pursuant to Section 491(d) of the FRCSRA.

Proposed Elements of the Federal Program

This notice announces the Department of Commerce's intention to issue regulations implementing the ban on the export of state timber originating in the 15 States identified in the Order which have not had programs approved or had FRCSRA's prohibitions modified or removed pursuant to Section 491(h). Before drafting regulations, however, the Department seeks comments from interested parties on the following proposed elements of the Federal Program:

1. *Procedures to identify and mark State timber.* Pursuant to section 491(c)(1) of the FRCSRA, the Department proposes to require *owners/purchasers* of State timber:

(a) To identify and paint, by means described at subparagraphs (b) and (c) of this paragraph, State timber (sometimes hereafter ''logs requiring domestic processing'');

(b) To use highway yellow paint to identify logs requiring domestic processing. Before removal from the harvest area, the owner must paint each log at each end with a spot of highway yellow paint not less than three inches square;

(c) To retain the identification placed on an unprocessed log until the log is domestically processed. If a log is cut into two or more segments before processing, the owner is required to identify each segment in the same manner as the original log. The marking requirement would include all State timber;

2. *Procedures for documenting transfers of State timber.* Pursuant to Sections 492(a)(3) and 492(a)(4) of the FRCSRA, the Department proposes to require the following reporting procedures for the receipt and disposition of the unprocessed public timber:

(a) *Documenting the transfer of unprocessed State timber.* Each person who transfers to another person State timber must, before completing the transfer:

(i) Provide to the other person a written document identifying the public lands from which the timber originated and giving notice to the person of the prohibition against exporting the State timber or substituting it for exported private timber;

(ii) receive from the purchaser written acknowledgement of the notice, and a written agreement that the recipient of the timber will comply with all the requirements of the FRCSRA; and

(iii) provide annually to the Secretary of Commerce copies of all notices, acknowledgements, and agreements referred to in paragraphs (3)(a)(i) and (3)(a)(ii).

(b) *Documenting the acquisition of unprocessed State timber.* Each person who directly or indirectly acquires or processes State timber shall report the receipt and disposition of the timber to the Secretary of Commerce as follows:

(i) the source of the State timber acquired.

(ii) from whom the timber was acquired and to whom the timber was sold, transferred or otherwise conveyed; and

(iii) an accounting by source, in net board feet Scribner, or cubic feet, of the volume of State timber acquired, the volume domestically processed by the purchaser and the volume sold for domestic processing.

This requirement would apply to all intermediate parties until a purchaser sends the logs to a domestic sawmill and they are processed;

3. *Procedures for assessing civil penalties and applying administrative remedies for violations of the FRCSRA.* Pursuant to Section 492(c)(1)(B), if the Secretary of Commerce finds, on the record and after an opportunity for a hearing, that a person has exported or caused to be exported State timber with willful disregard of the Secretary's Orders, the Secretary may assess a civil penalty on such person. The civil penalty may be up to $500,000 for each violation or 3 times the gross value of unprocessed timber involved in the violation, whichever amount is greater.

Pursuant to Section 492(c)(2)(B), if the Secretary of Commerce finds on the record and after an opportunity for a hearing, that a person has violated any provision of the FRCSRA or any regulation issued under the FRCSRA relating to the export of unprocessed timber originating from public lands, whether or not the violation caused the export of unprocessed timber from public lands in violation of the FRCSRA, the Secretary may impose a civil penalty of up to $75,000 for each violation or up to $500,000 depending on the nature of the violation.

4. *Definition.* Pursuant to Section 493(7) of the FRCSRA, the term unprocessed timber means trees or portions of trees or other roundwood not processed to standards and specifications suitable for end product use. It does not include among other things chips, pulp, or pulp products and pulp logs or cull logs.

Petitions for Minimizing the Reporting Burdens on Those States That Do Not Export Timber From Public Lands

The Department is aware that a number of the states subject to the export ban have very small state timber sales volumes or do not sell state timber at all. The Department also is aware that some states do not have any unprocessed timber exported from state public lands. The Department is prepared to consider requests from such states for removal or modification of state restrictions, including reporting requirements of the Federal Program, pursuant to section 491(h) of the FRCSRA.

Particularly Useful Comments

The Department invites written comments from interested parties that may assist it in implementing the Federal Program. Specifically, information concerning the following would be particularly useful:

1. Under what circumstance should the Secretary include substitution as part of the rules for the Federal Program?

2. Are the Department's procedures for identifying and marking export-restricted State timber adequate to track such timber and prevent unauthorized export? Should the Department require persons/purchasers of State timber to hammer brand a log on each end with a brand approved for use by the Forest Supervisor of the State Forest in each affected State?

3. Are there more cost-effective ways to identify and track export-restricted State timber?

4. Is the Department's annual reporting requirement sufficient to track the flow of State timber?

Comment Procedures

The Department will consider public comments in the development of proposed regulations. The Department encourages interested persons who wish to comment to do so at the earliest possible time to permit the fullest consideration of their views.

The following procedures will apply to any comments submitted pursuant to this procedure:

1. Interested parties are invited to submit written comments (3 copies), opinions, data, information, or advice with respect to this notice to the address above by the dates specified above.

2. The Department will consider all comments received by the close of the comment period in developing proposed regulations. While comments received after the end of the comment period will be considered if possible, this cannot be assured.

3. All public comments on this advanced notice of proposed rulemaking will be a matter of public record and will be available for public inspection and copying. (Communications from agencies of the United States Government or foreign governments will not be made available for public inspection).

4. In the interest of accuracy and completeness, the Department requires comments in written form. Oral comments must be followed by written memoranda which will also be a matter of public record and will be available for public review and copying.

5. The Department will *not* accept public comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the person submitting the comments and will *not* consider them in the development of final regulations, and;

6. The comments received in response to this notice will be maintained in the Bureau of Export Administration, Freedom of Information Records Inspection Facility, Room 4525, Department of Commerce, 14th Street and Pennsylvania Avenue, N.W., Washington, DC 20239. Interested parties may inspect and copy records in this facility, including written public comments and memoranda summarizing the substance of oral communications, in accordance with regulations published in Part 4 of Title 15 of the Code of Federal Regulations. Information about the inspection and copying of records may be obtained from Margaret Cornejo, Bureau of Export Administration, Management Analyst, at the above address or by calling (202) 482–5653.

Rulemaking Requirements

The rule which is likely to be proposed based on this notice was determined to be significant under Executive Order 12866.

Dated: June 2, 1995.

Sue E. Eckert,

Assistant Secretary for Export Administration.

[FR Doc. 95–14038 Filed 6–6–95; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 95N–0033]

Dental Devices; Effective Date of Requirement for Premarket Approval of Endodontic Dry Heat Sterilizer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the endodontic dry heat sterilizer, a medical device. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements, and the benefits to the public from use of the device. In addition, FDA is announcing the opportunity for interested persons to request the agency to change the classification of the device based on new information.

DATES: Written comments by September 5, 1995; requests for a change in classification by June 22, 1995. FDA intends that, if a final rule based on this proposed rule is issued, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

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

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device, subject to the rulemaking procedure under section 515(b) of the act, is not required to have an approved investigational device exemption (IDE) (21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device.

Section 515(b)(2)(A) of the act provides that a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The proposed rule; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change of classification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act provides that FDA shall, after the close of the