

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

comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval, or publish a notice terminating the proceeding. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is made final, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or a notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after final classification of the device under section 513 of the act, whichever is later. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). FDA has in the past requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for endodontic dry heat sterilizers.

The act does not permit an extension of the 90-day period after issuance of a final rule within which an application or a notice is required to be filed. The House Report on the amendments states that:

the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval.

(H. Rept. 94-853, 94th Cong., 2d sess. 42 (1976).)

A. Classification of Endodontic Dry Heat Sterilizers

In the **Federal Register** of August 12, 1987 (52 FR 30082), FDA issued a final rule (§ 872.6730 (21 CFR 872.6730)) classifying the endodontic dry heat sterilizer into class III. The preamble to the proposal to classify the device published in the **Federal Register** of December 30, 1980 (45 FR 86155), included the recommendation of the Dental Device Classification Panel (the panel), of the Medical Devices Advisory Committee, an FDA advisory committee, regarding the classification of the device.

The panel recommended that the device be in class III (premarket approval) because the device presented an unreasonable risk of illness or injury. According to the panel, the devices failed to sterilize adequately various endodontic and dental instruments. The panel felt that the failures could be the result of: (1) The device not reaching and maintaining an adequate temperature because of a faulty thermostat or (2) the result of unequal heat distribution by the glass beads throughout the well despite sufficient heat. The panel believed that it was not possible to establish an adequate performance standard for the device because satisfactory performance had never been demonstrated. The panel recommended the device to be subject to premarket approval to assure that manufacturers of the device demonstrate satisfactory performance and that further study was necessary to determine the causes of the device's ineffectiveness.

FDA agreed with the panel's recommendation that endodontic dry heat sterilizers be classified into class III. FDA believed that there was an unreasonable risk of illness or injury because of the potential failure of the device to sterilize dental instruments adequately. FDA believed that there was inadequate information to determine if general controls or a performance standard would provide reasonable assurance of safety and effectiveness.

B. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for the endodontic dry heat sterilizer within 90 days after issuance of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing the

endodontic dry heat sterilizer during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that, under section 515(d)(1)(B)(i) of the act, FDA may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the agency finds that " * * * the continued availability of the device is necessary for the public health."

FDA intends that, under § 812.2(d), the preamble to any final rule based on this proposal will state that, as of the date on which a PMA or a notice of completion of a PDP is required to be filed, the exemptions in § 812.2 (c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any endodontic dry heat sterilizer which is: (1) Not legally on the market on or before that date; (2) legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date; or (3) for which PMA approval has been denied or withdrawn.

If a PMA or a notice of completion of a PDP for the endodontic dry heat sterilizer is not filed with FDA within 90 days after the date of issuance of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. FDA would not consider an investigation of an endodontic glass bead sterilizer to pose a significant risk as defined in the IDE regulation provided that instruments processed in the device are terminally sterilized by a sterilization process which can be biologically monitored, such as steam, ethylene oxide, or dry heat. If the investigation cannot be so designed, the investigation would constitute a significant risk. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period after the final rule is published to avoid interrupting investigations.

C. Description of Device

Endodontic dry heat sterilizers are small electrically heated dry heat sterilizers with a central well containing a heat transfer medium. The types of

heat transfer media used in these units have included glass beads, molten metal, metal beads, and salt. The instruments which are to be sterilized are inserted directly into the heat transfer medium. The units are defined in § 872.6730 as devices used to sterilize endodontic and other dental instruments by the application of dry heat which is supplied by the glass beads which have been heated by electricity.

The proposed rule to require premarket approval of the endodontic dry heat sterilizer applies to devices that were being commercially distributed before May 28, 1976, and to devices that were introduced into commercial distribution since that date which have been found to be substantially equivalent to predicate endodontic dry heat sterilizers.

D. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring endodontic dry heat sterilizers to have an approved PMA or a declared completed PDP; and (2) the benefits to the public from the use of the device.

E. Risk Factors

The panel identified the primary risk to health as infection by stating that "The inability of the device to sterilize adequately endodontic and other dental instruments may lead to transmission of microorganisms among patients and subsequent spread of infection."

A review of the literature on endodontic dry heat sterilizers has identified the following problems associated with the use of these devices which contribute to the inability of endodontic dry heat sterilizers to sterilize instruments, including general medical instruments.

1. Temperature Variation Within the Well

There are many reports in the literature describing the temperature variation found within the wells of glass bead sterilizers (Refs. 2, 3, 4, 7, 10, and 11). Engelhardt et al. (Ref. 4) measured the temperature distribution in four brands of glass bead sterilizers at two different sites from the center and at six different depths in the well. He reported that the temperature within the well varied significantly depending upon location. The temperature was highest closest to the wall and midway down from the surface (Ref. 4). Corner also reported that near the periphery of the

well the temperature varied by as much as 10 °C over time (Ref. 5). According to Ingle, glass bead sterilizers should not be used as a substitute for dry heat convection or steam sterilizers because of the temperature variations (Ref. 7).

2. Lack of Methods to Monitor the Recommended Exposure Times for Sterilization of the Instruments

The manufacturers' recommended exposure times for sterilization of instruments vary from as short as 2 seconds to 45 seconds for sterilizers whose purported operating temperatures are from 218 °C to 260 °C. However, location of the instruments in the well, the size and mass of the instruments, the number of instruments, and the shape of the instruments must be factored into the amount of time required for sterilization. Larger instruments composed of more metal take more time to heat than smaller instruments. Koehler reported that the time required to raise an instrument's temperature was dependent upon its size. Small instruments such as root canal files heated rapidly, while large instruments such as cotton pliers never reached the specified operating temperature (Ref. 6). Corner reported that instruments such as forceps, scalpels, spatulas, and scissors sterilized in rapid succession caused the temperature in the well to drop an average of 7 °C for each instrument and that it took 15 minutes for the temperature of the well to recover (Ref. 2). Smith reported sterilization times of 15 seconds to kill orthodontic bands contaminated with *Staphylococcus albus* and 45 seconds for bands contaminated with *Bacillus subtilis* spores; but if five bands were sterilized simultaneously, then the sterilization times doubled (Ref. 10). Fahid reported that a No. 60 file, which was the largest file tested in the study, was the most difficult to sterilize. The difficulty was attributed to two factors: the large mass of the file, and the air trapped in the deep trough since air is a poor heat conductor (Ref. 5). Engelhardt described sterilization times for endodontic instruments ranging from 15 to more than 100 seconds in glass bead sterilizers, and in some cases, the 100 seconds were not sufficient to achieve sterilization (Ref. 4). Schutt et al. found that it took 60 seconds to sterilize dental burs. He also emphasized that the temperature at the depth of the immersion of the burs should be measured and that the minimum temperature should be at least 175 °C at 2 millimeters (mm) below the surface and 240 °C at 15 mm below the surface (Ref. 9). It has been reported in the

literature that glass bead sterilizers have been shown to be effective only with small instruments that can be imbedded into the heat transfer media and that their effectiveness has not been demonstrated for instruments of larger bulk. The insertion of large instruments would reduce the temperature of the glass beads below the minimum temperature required for sterilization (Ref. 1). Heat conduction in a large, partially imbedded device would be variable.

Precleaning of the instruments before insertion into the glass bead sterilizer is critical to the effectiveness of the device. Engelhardt demonstrated that if endodontic instruments were contaminated with a protein load (blood), the time required for sterilization was more than doubled. Such adverse conditions can easily be found in infected or gangrenous pulp. Spores, which are more resistant to sterilization processes than vegetative organisms, have been found in the oral cavity and cultured from pulp material (Ref. 4).

3. Lack of Methods to Monitor the Performance/Sterilization Efficacy of the Device

There are no identified methods for the routine monitoring of the sterilization efficacy of the endodontic dry heat sterilizer such as the ones which exist with the traditional sterilization methods, i.e., steam autoclaves, hot air dry heat sterilizers, or ethylene oxide sterilizers. Chemical and biological indicators are available for routine monitoring of the efficacy of the cycle parameters and for the validation of the process specifications for these traditional sterilizers. The data in the literature, as noted above, suggest that the user can not be assured that instruments inserted into an endodontic dry heat sterilizer will be reliably exposed to the minimum cycle parameters required for sterilization, i.e., exposure of the device to a set temperature for a specified time.

4. Variability of the Warm-up Times for Glass Bead Sterilizers

Reported warm-up times for these devices range from 15 minutes to 50 minutes with the average of 15–20 minutes. However, Corner reported that it took up to 30 minutes for the temperature of the glass beads to stabilize even though the manufacturer claimed that the device reached operating temperature within 10 minutes (Ref. 2).

5. Maintenance of Sterility After Removal From the Device

The instructions for use for most of the devices do not instruct the user on the proper procedure to remove instruments from the device, and on how to maintain sterility of the instruments or the processed portion of the instrument during the cool down period. There also exists the possibility that the heat transfer medium could serve as a source of contamination between patients. Because of the reported temperature gradients within the wells, there exists the possibility that heat resistant microorganisms could survive in the cooler regions near the top of the well and contaminate the instruments used upon the next patient as they are removed from the well. Furthermore, because endodontic dry heat sterilizers only process that portion of the instrument which has been inserted into the glass beads, there is the potential of contaminating a sterile field with a device which had not been properly processed.

6. Possibility of the Heat Transfer Medium Remaining Upon The Devices

Occasionally the heat transfer media has been observed to adhere to wet instruments. If the particles are not detected before the devices are inserted into the site, then they could cause blockage of the wound site or other adverse effects. This would cause significant problems if the heat transfer media were glass beads or molten metal (Ref. 1).

F. Benefit of the Devices

The endodontic dry heat sterilizer could be used to decontaminate endodontic instruments during a procedure on a single patient provided the instruments are properly cleaned to remove organic debris before insertion into the unit. In theory the number of microorganisms that would be introduced into the same site or into a new site on the same patient during a single procedure would be reduced. Once the procedure is over, the instruments should be processed using traditional methods of decontamination and sterilization before use in the next patient.

G. Need for Information for Risk/Benefit Assessment of the Device

The data in the literature indicate the lack of uniform sterilization parameters among the various glass bead sterilizers which have been marketed. Because of the temperature variation found within the wells of glass bead sterilizers, exposure of an instrument to an adequate sterilizing temperature is

difficult to determine and must be confirmed independently for each instrument. Also determination of the sterilization exposure time is dependent upon instrument size and mass. As Koehler noted, some instruments never reach the appropriate temperature because of their size and mass (Ref. 6); and, as noted in the American Dental Association's "Accepted Dental Therapeutics," 40th ed., endodontic dry heat sterilizers are not appropriate for large bulk instruments (Ref. 1).

Review of the claims being made for these devices suggests that manufacturers are expanding the claims beyond those originally defined in § 872.6730. The claims have been expanded to include the sterilization of general medical instruments and electrolysis and acupuncture needles, and to devices not regulated by FDA such as manicurist's instruments. The claims imply that these devices can be used as a substitute for the traditional methods of sterilization. Scarlett noted that endodontic dry heat sterilizers are not sterilizers, but are decontaminating devices and that they should not be used to sterilize instruments between patients (Ref. 8). No system exists for (1) Monitoring the exposure of the instrument to sterilization conditions, or (2) demonstrating that the sterilization exposure parameters have been achieved within the well. Only the portion of the instrument which is inserted into the heat transfer medium has the potential of being sterilized; the portion which is not inserted into the glass beads is not sterilized. The use of endodontic dry heat sterilizers with general medical instruments and with the implication as a substitute sterilization method raises serious safety and effectiveness questions which the manufacturers of these devices have not adequately addressed. There is the serious risk of infection through the use of inadequately processed instruments.

FDA believes that sufficient information may exist regarding the risks and benefits associated with the device, but the information must be assembled in such a way as to enable FDA to determine if the information provides reasonable assurance of the safety and effectiveness of the device for its intended use as defined in 21 CFR 860.7.

FDA classified the endodontic dry heat sterilizer into class III because it determined that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance. FDA has determined that the

special controls that may now be applied to class II devices under the Safe Medical Devices Act of 1990 also would not provide such assurance. FDA has weighed the probable risks and benefits to the public health from the use of the device and believes that the literature reports and other information discussed above present evidence of significant risks associated with use of the device. These risks must be addressed by the manufacturers of endodontic dry heat sterilizers. FDA believes that the endodontic dry heat should undergo premarket approval to establish effectiveness and to determine whether the benefits to the patient are sufficient to outweigh any risk.

II. PMA Requirements

A PMA for this device must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified above, as well as a discussion of the effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence obtained from well-controlled studies, with detailed data, in order to provide reasonable assurance of the safety and effectiveness of the endodontic dry heat sterilizer for its intended use. The data must include the following information:

- a. A general description of the sterilizer including its specifications, process parameters and process monitors;
- b. An overview of the sterilization process with accompanying charts, graphs, or other visuals explaining all parameters;
- c. A description of any test packs used in validating the performance of the endodontic dry heat sterilizer and in routine monitoring of the device;
- d. Physical tests which demonstrate that the sterilizer achieves and maintains the physical process lethality conditions within specifications. The testing should describe how the process parameters and specifications were determined;
- e. The microbiological performance tests must demonstrate that the device can sterilize to an acceptable sterilization assurance level all medical products identified in the labeling when used in accordance with the directions for use. The tests should be consistent with those used to validate sterilization processes including simulated and actual use tests;
- f. Material compatibility tests must show that the medical devices identified in the labeling are compatible with the

sterilization process of the endodontic dry heat sterilizer; and

g. Final qualification tests from at least three consecutive runs under worst case loading conditions as indicated in the labeling.

Additional information about the validation of sterilization processes can be found in: "Guidance on Premarket Notification (510(k)) Submissions for Sterilizers Intended for Use in Health Care Facilities" (available upon request from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850); the American Association of Medical Instrumentation's (AAMI) voluntary standards describing the validation requirements for sterilization processes; and the publication entitled "Sterile Medical Devices, A GMP Workshop Manual, 4th Ed., HHS Publication (FDA) 84-4147.

The PMA should contain a detailed discussion with supporting simulated- and in-use studies, as described in the above guidance, of: (1) All risks that have been identified in this proposed rule; and (2) the effectiveness of the specific endodontic dry heat sterilizer that is the subject of the application. In addition, the submission should contain all data and information on: (1) Risks known to the applicant that have not been identified in this proposed rule; (2) summaries of all existing simulated- and in-use data from investigations on the safety and effectiveness of the device for which premarket approval is sought; and (3) the results of simulated- and in-use studies conducted by or for the applicant. Applicants should submit any PMA in accordance with the FDA's "Guideline for the Arrangement and Content of a PMA Application." The guideline is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (address above).

III. Comments

Interested persons may, on or before September 5, 1995, 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 or requests are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. Opportunity to Request a Change in Classification

Before requiring the filing of a PMA or a notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of the endodontic dry heat sterilizer is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by June 22, 1995.

The agency advises that, to ensure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of the endodontic dry heat sterilizer is submitted, the agency will, by August 7, 1995, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130 of the regulations.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. American Dental Association, "Accepted Dental Therapeutics," 40th ed., pp. 138-139, Chicago, IL, 1984.
2. Corner, G. A., "An Assessment of the Performance of a Glass Bead Sterilizer," *Journal of Hospital Infection*, 10:308-311, 1987.
3. Dayoub, M. B., and M. J. Devine, "Endodontic Dry-Heat Sterilizer Effectiveness," *Journal of Endodontics*, 2:343-344, 1976.
4. Engelhardt, M. P., L. Grun, and H. Dahl, "Factors Affecting Sterilization in Glass Bead Sterilizers," *Journal of Endodontics*, 10:454-470, 1984.
5. Fahid, A., and J. F. Tainter, "The Influence of File Size, Cleaning, and Time on the Effectiveness of Bead Sterilizers," *Oral Surgery*, 58:443-445, 1984.

6. Koehler, H. M., and J. J. Hefferren, "Time-Temperature Relations of Dental Instruments Heated in Root-Canal Instrument Sterilizers," *Journal of Dental Research*, 41:182-195, 1962.
7. Ingle, J. I., *Endodontics*, 3d Ed., Philadelphia, Lea & Febiger, pp. 615-616.
8. Jakush, J., "Infection Control Procedures and Products: Cautions and Common Sense," *Journal of The American Dental Association*, 117:293-301, 1988.
9. Schutt, R. W., and W. J. Starsiak, "Glass Bead Sterilization of Surgical Dental Burs," *International Journal of Oral and Maxillofacial Surgery*, 19:250-251, 1990.
10. Smith, G. E., "Glass Bead Sterilization of Orthodontic Bands," *American Journal of Orthodontics Dentofacial Orthopedics*, 90:243-249, 1986.
11. Windeler, A. S., and R. G. Walter, "The Sporidical Activity of Glass Bead Sterilizers," *Journal of Endodontics*, 1:273-275, 1975.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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 PMA's for this device could have been required by FDA as early as February 12, 1990, and because firms that distributed this device prior to May 28, 1976, or whose device has been found by FDA to be substantially equivalent will be permitted to continue marketing the endodontic dry heat sterilizer during FDA's review of the PMA or notice of completion of the

PDP, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 is revised to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

2. Section 872.6730 is amended by revising paragraph (c) to read as follows:

§ 872.6730 Endodontic dry heat sterilizer.

* * * * *

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (90 days after the effective date of a final rule based on this proposed rule), for any endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976, or that has on or before (90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to the endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976. Any other endodontic dry heat sterilizer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: May 24, 1995.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-13831 Filed 6-6-95; 8:45 am]

BILLING CODE 4160-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[TX-001; FRL-5217-7]

Clean Air Act Proposed Interim Approval Operating Permits Program for the State of Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed interim approval.

SUMMARY: The EPA proposes source category-limited interim approval of the operating permits program submitted by the Governor of Texas for the State of Texas for the purpose of complying with Federal requirements which mandate that States develop and submit to EPA programs for issuing operating permits to all major stationary sources, with the exception of sources on Indian Lands. Source category-limited interim approval was specifically requested by the Governor for this submission.

DATES: Comments on this proposed action must be received in writing by July 7, 1995.

ADDRESSES: Written comments on this action should be addressed to Ms. Jole C. Luehrs, Chief, New Source Review (NSR) Section, at the EPA Region 6 Office listed below. Copies of the State's submittal and other supporting information used in developing the proposed interim approval are available for inspection during normal business hours at the following locations. Interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before visiting day.

Environmental Protection Agency,
Region 6, Air Programs Branch (6T-AN), 1445 Ross Avenue, Suite 700,
Dallas, Texas 75202-2733.
Texas Natural Resource Conservation
Commission, Office of Air Quality,
12124 Park 35 Circle, Austin, Texas
78753.

FOR FURTHER INFORMATION CONTACT: David F. Garcia, New Source Review Section, Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733, telephone 214-665-7217.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

A. Introduction

As required under title V of the Clean Air Act, as amended on November 15, 1990 ("the Act"), the EPA has promulgated rules which define the minimum elements of an approvable

State operating permits program and the corresponding standards and procedures by which the EPA will approve, oversee, and withdraw approval of a State operating permits program (see 57 **Federal Register** 32250, July 21, 1992). These rules are codified at 40 Code of Federal Regulations (CFR) part 70 ("the part 70 regulation"). Title V requires States to develop, and submit to the EPA, programs for issuing these operating permits to all major stationary sources and to certain other sources.

The Act requires that States develop and submit these programs to the EPA by November 15, 1993, and that the EPA act to approve or disapprove each program within one year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act and the part 70 regulation which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of part 70, the EPA may grant the program interim approval for a period of up to two years. Where a State requests source category-limited interim approval and demonstrates compelling reasons in support thereof, the EPA may also grant such an interim approval. If the EPA has not fully approved a program by two years after the date of November 15, 1993 or by the end of an interim program, it must establish and implement a Federal program.

B. Federal Oversight and Sanctions

If the EPA were to finalize this proposed source category-limited interim approval, it would grant that approval for a period of two years following the effective date of final interim approval, and the interim approval could not be renewed. During the interim approval period, the State of Texas would be protected from sanctions, and the EPA would not be obligated to promulgate, administer, and enforce a Federal permits program for the State of Texas. Permits issued under a program with interim approval have full standing with respect to part 70, and the State will permit sources based on the transition schedule provided in Regulation XII, Title 31 of the Texas Administrative Code (TAC).

Following final interim approval, if Texas has failed to submit a complete corrective program for full approval by the date six months before expiration of the interim approval, the EPA would start an 18-month clock for mandatory sanctions. If Texas then failed to submit a corrective program that the EPA found complete before the expiration of that 18-month period, the EPA would be required to apply one of the sanctions