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