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 simulatedand 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 inuse 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 Reguest 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.

- American Dental Association, "Accepted Dental Therapeutics," 40th ed., pp. 138– 139, Chicago, IL, 1984.
 Corner, G. A., "An Assessment of the
- 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.
- Engelhardt, M. P., L. Grun, and H. Dahl, "Factors Affecting Sterilization in Glass Bead Sterilizers," *Journal of Endodontics*, 10:454–470, 1984.
- 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.

- 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.
- Jakush, J., "Infection Control Procedures and Products: Cautions and Common Sense," *Journal of The American Dental Association*, 117:293–301, 1988.
- 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.
- 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 Sporicidal Activity of Glass Beads 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