

addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/opacom/background/voice.html>. Comments are to be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is conducting a pilot premarket review program and is soliciting participation from the medical device industry. The pilot program is intended to evaluate the utility of an alternative submission procedure as described in the draft STED document prepared by SG1 of the GHTF. The document seeks to harmonize the different requirements for premarket submissions in various countries.

The GHTF is a voluntary group comprised of medical device regulatory officials and industry representatives from the United States, Canada, Australia, the European Union, and Japan. The goals of the GHTF are to: (1) Encourage convergence in regulatory practices with respect to ensuring the safety, effectiveness, performance, and quality of medical devices; (2) promote technological innovation; and (3) facilitate international trade. The GHTF's Web site can be accessed at <http://www.ghftf.org>. It provides further information concerning the organization's structure, goals, and procedures.

The pilot premarket review program (STED pilot program) as implemented in the United States by FDA, will rely on the FDA final guidance that is the subject of this notice, and four related documents that are appended to the guidance. These documents are: (1) A letter to the global medical device

industry announcing the pilot program (Appendix 1); (2) the draft STED document created by SG1 of GHTF (Appendix 2); (3) the GHTF SG1 final document entitled "Essential Principles of Safety and Performance of Medical Devices," known as "Essential Principles" (Appendix 3); and (4) the document entitled "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry," issued in October 2002 (Appendix 4).

The FDA guidance document is intended to assist the medical device industry in making submissions to FDA that use the draft STED document format and are consistent with U.S. requirements. The announcement letter provides useful background and summary information regarding the proposed pilot premarket review program. The draft STED document describes a proposed internationally harmonized format and content for premarket submissions, e.g., PMA applications and 510(k) submissions in the United States, based on conformity to the Essential Principles. The Essential Principles are general and specific safety and performance recommendations for medical devices. They were developed by GHTF and are listed in the third document appended to the guidance. A discussion of the least burdensome provisions is provided in the fourth document.

All five of the founding members of the GHTF are participating in the pilot program. They include the United States, Canada, Australia, the European Union, and Japan. Each of the participants will provide specific directions for implementing the pilot program within its own jurisdiction.

The GHTF seeks to assess the international utility of the draft STED document. Therefore, SG1 of GHTF is encouraging manufacturers to prepare submissions using the draft STED document for a particular device to as many of the participating GHTF member countries as possible. SG1 also encourages manufacturers to use the draft STED document for submissions that cover a range of devices having different regulatory classes. Candidate devices that have already been identified to be of mutual interest to the GHTF members are set forth in the guidance.

FDA intends to process premarket submissions prepared using the draft STED document within statutory time limits and with review times comparable to other submissions for similar products. There will be no expedited review of submissions unless

the device merits such review under current policies.

FDA plans to conduct the STED pilot program for a period of 1 year. The pilot will begin on the date of publication of the final FDA guidance document. FDA will assess the pilot during its course and may choose to decline receipt of additional submissions using the format described in the draft STED document (draft STED format) to assess the initial experiences. At the end of the pilot, FDA and other GHTF participants will analyze the outcome to determine whether the draft STED document is a viable alternative to current premarket submission procedures and whether the program should be continued or expanded. FDA will post on its Web site a report of the outcome of the pilot program.

FDA published a draft of the FDA guidance document in the **Federal Register** of July 25, 2001 (66 FR 38714). The comment period ended on September 24, 2001. FDA received comments from five parties; in some instances the parties submitted multiple comments. FDA's responses are provided in section II of this document. In addition, FDA is planning to have SG1 review the comments and provide recommendations at the time it revises the draft STED document. This would occur at the end of the pilot program.

II. Comments and Responses

(Comment 1) One comment states that harmonization is a barrier to entry in the marketplace for smaller companies. The comment expresses concern that the Essential Principles referenced in the draft STED document will add more premarket notification (510(k)) requirements for those seeking to obtain FDA clearance for their medical devices.

FDA believes the draft STED document, and the associated FDA guidance document describing how FDA intends to implement the pilot premarket program, do not present significant new impediments for persons intending to market their devices using the 510(k) process. There are no new requirements expected under the pilot program for registration or quality systems implementation before a person submits a 510(k) using the draft STED format. The example, manufacturing information, is not ordinarily required in a 510(k) submission. The same would be true for a submission using the draft STED format. A manufacturer, however, must be registered and a quality system must be in effect when a device is marketed.

(Comment 2) One comment supports the harmonization process and requests that table 1 in the FDA guidance