

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Medical Devices: A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Final Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised final guidance entitled "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff." This revised guidance extends by 1 year a voluntary pilot premarket review program that may reduce the burden on manufacturers who face conflicting premarket submission format and content requirements in different countries. The pilot program is intended to evaluate the utility of an alternative submission procedure as described in the document entitled "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices" (draft STED document). The draft STED document was developed by Study Group 1 (SG1) of the Global Harmonization Task Force (GHTF) and issued as a working draft in December 2000. 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. Each of these member countries will participate in the pilot program and will provide

specific directions for implementing the program within their respective jurisdictions.

DATES: Submit written comments at any time. The pilot program is extended until June 25, 2005.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff” to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-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: Harry R. Sauberman, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–4879, e-mail: hrrs@cdrh.fda.gov; or Eric J. Rechen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186, e-mail: ejr@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 26, 2003 (68 FR 38068), FDA announced the availability of a guidance document entitled “A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff.” The guidance document announced a pilot premarket review program and solicited 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 June 26, 2003, guidance and notice of availability announced that the pilot program would be in effect for 1 year from the date of publication of the notice of availability. In this revised guidance, FDA is extending the pilot program for 1 more year. Other than updated contact information, there are no other changes to the guidance document. FDA received no comments on the guidance document. The revised guidance is a level 2 guidance under FDA’s good guidance practices (GGPs) regulation (21 CFR 10.115). As such, FDA made the guidance available on its Web site on July 6, 2004.

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 include the following items: (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.gh tf.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.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGP's regulation (21 CFR 10.115). The guidance represents the agency's current thinking on a way to apply GHTF recommendations as related to premarket submission to FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

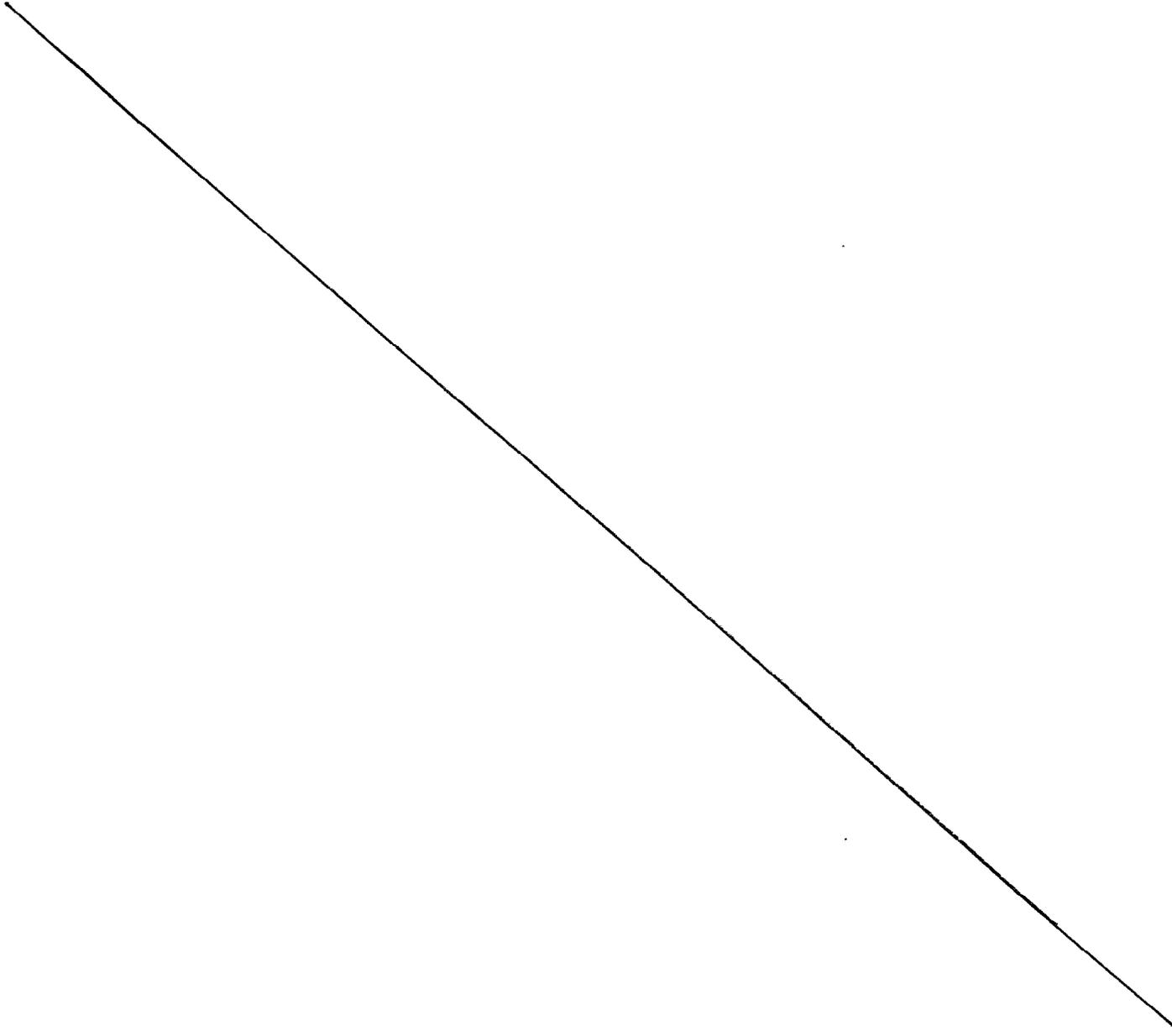
III. Electronic Access

You may obtain a copy of "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff," via fax machine by calling the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1347) followed by the pound sign. Follow the remaining voice prompts to complete your request.

You may also obtain a copy of the guidance through the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH home page is updated on a regular basis and includes: Civil money penalty guidance documents, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), assistance for small manufacturers, information on video conferencing, electronic submissions, mammography devices, and other device-related information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of



this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/16/04

July 16, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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