or

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SUPPLEMENTARY INFORMATION:

I. The Consolidation Initiative

A. Therapeutic Biological Products Transferred to CDER

As of June 30, 2003, responsibility for regulating most therapeutic biologics, with certain exceptions (e.g., cell and gene therapy products and therapeutic vaccines) will be transferred from the Office of Therapeutics Research and Review (OTRR), CBER, to the Office of New Drugs (OND), and the Office of Pharmaceutical Science (OPS), CDER. Initially, this transfer of products will take place as the divisions of OTRR within CBER are detailed to offices within CDER. As of June 30, 2003:

- The Division of Therapeutic Proteins and the Division of Monoclonal Antibodies of OTRR, CBER, will be detailed to OPS, CDER.
- The Division of Clinical Trial Design and Analysis, the Division of Application Review and Policy, and the immediate office of the Director, OTRR, CBER, will be detailed to OND, CDER.

FDA anticipates that as of the start of fiscal year 2004 on October 1, 2003, the offices detailed to CDER will be incorporated into CDER's organizational structure, including the creation of a new Office of Drug Evaluation (ODE) in OND, CDER.

B. Therapeutic Biological Products Remaining in CBER

Under a previous reorganization, cell and gene therapy products from the Division of Cellular and Gene Therapies, OTRR, CBER were transferred to a new office, the Office of Cellular, Tissue and Gene Therapies (OCTGT).

Overall responsibility for therapeutic vaccines will remain in CBER. The clinical review of therapeutic vaccine-associated investigational new drug applications (INDs) and biologics license applications (BLAs) will be conducted by CBER and coordinated with the consolidated clinical expertise area in CDER.

II. Web Site Listing CBER Applications Transferred to CDER and Contact Information

FDA has created a Web site listing the identification numbers of the INDs, BLAs, investigational device exemptions, and new drug applications in CBER that are being transferred to CDER. Holders of all CBER applications are encouraged to check this Web site to determine which, if any, of their applications are being transferred and to find new contact information. The Web site address is: *http://www.fda.gov/cber/transfer/transfer.htm*. Until notified by CDER, submitters should continue to send submissions to the CBER Document Control Center.

III. Delegations of Authority

As a result of this product consolidation and the resulting changes to the organizational structure of CDER and CBER, the agency has conducted a comprehensive update of the delegations of authority to reflect organizational changes. Current program delegations of authority for CDER and CBER have been revised to reflect these changes. Delegations of authority give particular officials in the Centers the legal authority needed to take substantive actions and perform certain functions of the Commissioner of Food and Drugs. These changes will be made to the agency's Staff Manual Guide (SMG) system available on the Internet at *http://www.fda.gov/smg*. While comprehensive changes have been made to the delegations, the agency believes the current delegation at SMG 1410.702 provides CDER with all necessary authority for the premarket approval of any biological product for which CDER has oversight. Furthermore, revised SMG 1410.202 provides CDER with the necessary authority to perform all functions of the Director of CBER with respect to biological products transferred to CDER.

IV. Regulations Affected by the Product Consolidation

The agency is in the process of making technical amendments to its regulations affected by this reorganization and anticipates these revisions will be completed by the beginning of fiscal year 2004 on October 1, 2003, or shortly thereafter. Any revisions to FDA's regulations will be published in the **Federal Register** upon completion.

Dated: June 20, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16242 Filed 6–25–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0281]

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 final guidance entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff.'' This guidance is intended to assist the medical device industry and FDA staff in implementing 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 proposed pilot program will 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,'' otherwise known as the ''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. This guidance takes effect upon the date of its publication.

DATES: Submit written comments at any time.

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/backgrounder/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: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4692, e-mail: *tau@cdrh.fda.gov*; or Harry R. Sauberman, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879, e-mail: *hrs@cdrh.fda.gov*.

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.ghtf.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

document be revised to include computed tomography scanners and magnetic resonance imaging devices.

FDA agrees to expand the candidates list as requested and has amended table 1 of the FDA guidance document accordingly.

(Comment 3) Two comments requested that members of the GHTF coordinate the execution of the pilot program in their respective jurisdictions by including the same device categories and conducting the pilot program simultaneously. The comments suggested posting information about the pilot program on the GHTF Web site. Concern was expressed that the draft STED document will lead to an increase in the type and amount of information submitted in premarket applications.

FDA agrees that the pilot premarket program should be coordinated with other members of GHTF to the extent possible, and has made efforts to do so. FDA will work with the GHTF secretariat and the Chair of SG1 to post appropriate information regarding the pilot program on the GHTF Web site. FDA is sensitive to the concern that a harmonized format may recommend different or additional information from that customarily submitted in premarket submissions. The draft STED format is one means of normalizing the information submitted to many different regulatory authorities. The short-term effect may indicate some imbalances in the regulatory burden from one country to another, but the long-term expectation is that the benefits will outweigh any short-term effects and will be significant. FDA believes that harmonization of administrative and technical requirements is desirable; the GHTF's role in the STED pilot program is supplemented by the strength of its efforts in standards development activities, bilateral partnerships, and mutual recognition activities.

(Comment 4) Another comment requests clarification of the information needed to be included in the premarket submission for each Essential Principle and asks if every Essential Principle must be addressed. The comment also requests clarifications on terminology with respect to labeling.

The premarket submission should identify the Essential Principles that are applicable to the device and provide conformity information as explained in sections 7.1.1 and 7.1.2 of the draft STED document. It will not necessarily be the case that all Essential Principles will be applicable to a particular device. In addition, there may be more than one way to conform to an Essential Principle, e.g., by meeting a standard or demonstrating laboratory results from an appropriate bench test.

FDA agrees that the draft STED document should have clarifications with respect to labeling terminology and instructions for use. FDA will ask SG1 to consider this comment when it assesses the results of the pilot program.

(Comment 5) Two comments ask FDA to clarify which of the Essential Principles would be relevant in a premarket submission prepared using the draft STED format. They ask whether FDA intends for premarket submissions, based on the draft STED format, to be submitted in a tabular format as shown in Appendix B of the draft STED document and, if so, whether the table needs to be supplemented with supporting information.

FDA expects premarket submissions prepared using the draft STED format to identify and reference all applicable Essential Principles, as explained in sections 7.1.1 and 7.1.2 of the draft STED document. Also, 510(k) submissions and premarket approval applictions (PMAs) relying on the draft STED format must still address all applicable FDA requirements for 510(k)s or PMAs. With regard to format, the basic format for preparing a harmonized premarket submission is described in sections 6.1 and 6.3 of the draft STED document (see also section VII of the final FDA guidance). Each part of the submission can be subgrouped as described in section 7.0 of the draft STED document. Section 7.1.2 suggests that one method to format evidence of conformity information may be in tabular form as shown in the sample table in Appendix B of the draft STED document. Supporting information should be provided as needed regardless of format, particularly if recommended in a product-specific guidance. FDA accepts declarations or statements of conformity to FDA-recognized standards. Use of such declarations or statements may provide a benefit to a manufacturer by decreasing the amount of supporting documentation that needs to be submitted.

(Comment 6) Another comment notes a possible incorrect cross-reference in table 3 of the draft FDA guidance with regard to standards.

FDA has eliminated table 3 and has clarified the section.

(Comment 7) Three comments state that a risk analysis is not included in 510(k) and PMA submissions and therefore should not be included in harmonized premarket submissions using the draft STED document.

FDA has announced new guidance that includes a risk analysis in some 510(k) submissions. (*See http://www.fda.gov/cdrh/modact/special-controls.html*). A goal of the premarket harmonization process is to achieve a common submission in terms of format and content for all five participating members of the GHTF. Although FDA may not require a risk analysis for a new 510(k), it is a common request in other countries. Therefore, it is prudent for a device manufacturer intending to market a device globally, and who intends to use the draft STED format, to include a risk analysis in the submission.

(Comment 8) One comment asks for clarification of the note under table 2 of the draft FDA guidance concerning manufacturing information.

FDA has eliminated table 2 and clarified the information elsewhere in the document. The FDA final guidance document notes that manufacturing information will not be needed for 510(k)s using the draft STED format during the pilot program, unless that information would otherwise be submitted under current procedures for a particular device.

(Comment 9) One comment requests the draft STED document include links between the class of a device and the parameters applicable to the Essential Principles of safety and performance. The comment suggests changing the title of section 7.3 from ''Summary of Design Verification and Validation Documents'' to ''Summary of Design and Verification Data.'' The comment notes the title could imply the need for more documentation than what is intended.

FDA will ask SG1 to consider this comment when it assesses the results of the pilot program.

(Comment 10) One comment recommends the use of promissory statements when a regulatory authority requires country-specific information beyond that described in the draft STED document.

FDA accepts statements of conformity to recognized standards. These statements indicate a device meets a particular standard. FDA has no other provisions for promissory statements.

(Comment 11) Another comment notes that the draft STED document and appendices refer to data and information not usually submitted in 510(k)s and PMAs. It suggests there be an indication of the information not applicable for these types of submissions to minimize the submission burden.

FDA agrees with the comment and has noted that manufacturing information is not ordinarily required in a 510(k) application. Hence this information would not be needed in a

510(k) when using the draft STED format as described in the final guidance document.

(Comment 12) One comment inquires about incentives for manufacturers to participate in the pilot program. Related comments ask that FDA reconsider the devices eligible for the pilot program.

FDA is committed to ensuring that the FDA review process will not be unduly hindered if persons choose to follow the draft STED format. However, FDA cannot assure shorter review timeframes if the draft STED format is used. FDA believes that medical device companies with vision, leadership, a desire to influence the accelerating global harmonization effort, and the goal of ultimately reducing their regulatory burden, will participate in the pilot program. FDA has increased the list of eligible devices to provide more flexibility and believes the pilot program will help achieve an international uniformity of submissions.

(Comment 13) One comment asks that the pilot program focus only on 510(k)s, PMAs, and PMA supplements that are for high risk devices.

FDA has exempted from premarket evaluation virtually all the low risk devices that were subject to premarket requirements. Therefore, the candidates for the pilot program are of a moderate to high degree of risk. PMA supplements are not candidates for the pilot program.

(Comment 14) One comment asks that the same measures of success or failure of the pilot program be identified for all countries conducting the pilot and that FDA clearly define the criteria and analysis methods that will be used.

FDA agrees that measures of success and analytical methods should be clearly defined prior to initiation of the pilot. It is important to determine whether the core of a premarket submission can be based on the draft STED format. Both FDA and SG1 will track and assess whether: (1) There are significant impediments to filing and review of documents, (2) the STED harmonized format has utility for evaluating different regulatory classes of devices having different complexities, and (3) use of the STED harmonized format results in improved regulatory review times. FDA will post a report summarizing the results of its analysis of the pilot on its Web site.

(Comment 15) One comment notes that statutory and/or regulatory changes may be needed to fully implement the draft STED document concept of harmonized premarket submissions in the member countries.

Each of the five GHTF member countries has determined that the pilot program can proceed without the need for statutory or regulatory changes if current country-specific requirements are met. It remains to be determined how a STED document would be implemented if it becomes an alternative means of submission.

(Comment 16) One comment asks that FDA remove endosseous dental implants from the list of candidate devices for the pilot program. The comment notes that applying the harmonized process to these implants will not provide the agency with the necessary information on their safety and effectiveness.

FDA does not concur with the comment. The FDA draft guidance for the pilot premarket review program and the draft STED document both describe the need for applicants to consider country-specific information, including guidance documents, when preparing their premarket submissions for review. A premarket submission for an endosseous dental implant based on the draft STED format should consider all relevant available guidance documents.

III. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs 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.

IV. 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*.

V. 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: June 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16108 Filed 6–25–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0161]

Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is adding nonelectric biopsy forceps (classified in 21 CFR 876.1075, *Gastroenterology-urology biopsy instrument*) to the list of critical reprocessed single-use devices (SUDs) whose exemption from premarket notification requirements is being terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), is necessary in a premarket notification (510(k)). FDA is requiring submission of these data to ensure that reprocessed single-use nonelectric biopsy forceps are substantially equivalent to predicate devices, in accordance with MDUFMA.

DATES: These actions are effective June 26, 2003. Manufacturers of reprocessed