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Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-25), 1401 Rockville Pike, suite 200 N., Rockville, MD 20852, 301-827-0372.

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), CDER, 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 CDER are detailed to offices within CDER. As of June 30, 2003:

- The Division of Therapeutic Proteins and the Division of Monoclonal Antibodies of OTRR, CDER, 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, CDER, 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 CDER

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

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

II. Web Site Listing CDER 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 CDER that are being transferred to CDER. Holders of all CDER 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 CDER 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 CDER, the agency has conducted a comprehensive update of the delegations of authority to reflect organizational changes. Current program delegations of authority for CDER and CDER 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 CDER 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.

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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-