activities by Government agencies to small businesses.

The goal of this public workshop is to present information that will enable FDA-regulated food facilities (farms, manufacturers, processors, distributors, retailers, and restaurants) to better comply with the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and with food defense guidance, especially in light of growing concerns about food defense. Information presented will be based on agency position as articulated through regulation, guidance, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Food defense awareness, (2) ALERT: The basics, (3) FDA actions on bioterrorism legislation (food supply), (4) food recalls, (5) crisis management, (6) food defense technologies and methodologies, and other related topics. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food defense and increase voluntary compliance and food defense awareness.

Dated: January 31, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1865 Filed 2–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0031]

Global Harmonization Task Force, Study Groups 1, 2, and 4; New Proposed and Final Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of proposed and final documents that have been prepared by Study Groups 1, 2, and 4 of the Global Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

DATES: Submit written or electronic comments on any of the proposed documents byMay 7, 2007. After May 7, 2007, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For Study Group 1: Ginette Y. Michaud, Chairperson, GHTF, Study Group 1, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

For Study Group 2: Mary Brady, GHTF, Study Group 2, Office of Surveillance and Biometrics, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3458.

For Study Group 4: Jacqueline Welch, GHTF, Study Group 4, Office of Compliance, Center for Devices and Radiological Health (HFZ–320), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as the GHTF to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using its own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by three of the Study Groups (1, 2, and 4).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of its efforts, this group has developed proposed document SG1(PD)N044:2006. SG1(PD)N044:2006 (proposed document), entitled ''Role of Standards,'' provides guidance on the use of standards by a manufacturer when designing a medical device and, subsequently, when demonstrating the device conforms to relevant essential safety and performance criteria. FDA seeks comment on the document and particularly ''Section 5.2 Revision or Replacement of Recognised Standards.'' This section addresses the use of a recognized standard during the transitional period when it is being replaced by a revised version.

Study Group 4 was initially tasked with the responsibility of developing

guidance documents on quality systems auditing practices. As a result of its efforts, this group has developed document SG4(PD)N33R13:2006. SG4(PD)N33R13:2006 (proposed document), entitled ''Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 3: Regulatory Audit Reports,'' suggests a structure for audit reports used in multiple jurisdictions, promoting consistency and uniformity and should assist the auditor in preparing a report for use by multiple regulators and/or auditing organizations. Having reports that are consistent in content should facilitate the review and exchange of audit reports. Acceptance of audit reports by multiple regulators should eventually reduce the number of audits for manufacturers.

Study Group 2 was initially tasked with the responsibility of developing guidance documents that will be used for the exchange of adverse event reports. As a result of its efforts, this group developed SG2N54R8:2006. SG2N54R8:2006 (final document), entitled ''Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices,'' provides guidance on the type of adverse events associated with medical devices that should be reported by manufacturers to a National Competent Authority. It elaborates on the regulatory requirements existing in the participating member countries.

II. Significance of Guidance

These documents represent recommendations from the GHTF study groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

III. Electronic Access

Persons interested in obtaining a copy of the documents may also do so by using the Internet. The Center for Devices and Radiological Health (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. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH web site 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 these documents. 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 30, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–1864 Filed 2–5–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency(s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Reporting Form for the MCHB National Hemophilia Program Grantees and Hemophilia Treatment Center (HTC) Affiliates Having Factor Replacement Product (FRP) Programs—NEW

The Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) is planning to implement an annual reporting form required of grantees of the MCHB National Hemophilia Program and their HTC affiliates having a factor replacement product (FRP) program. The purpose of the form is to provide systematic information and data comprising a financial overview of the FRP programs of the HTCs receiving funding through grantees of the MCHB National Hemophilia Program. The proposed form will constitute a reporting requirement for the MCHB National Hemophilia Program grantees and their affiliate HTCs having FRP programs.

Data from the form will provide quantitative information on the financial and services provision aspects of each of the HTC FRP programs under each of the MCHB National Hemophilia Program grantees, specifically: (a) Patient FRP program participation, (b) FRP program revenue, (c) FRP program costs, (d) FRP program net income, and (e) use of FRP program net income. This form will provide data useful to grantees and their affiliate HTCs having FRP programs. Useful data will also be provided to the MCHB National Hemophilia Program in order to assess FRP program performance including FRP program operational costs appropriateness, FRP program cost efficiency, and FRP program services benefits-information that is essential to evaluating HTCs having FRP programs, grantees, and the MCHB National Hemophilia Program.

Each HTC having an FRP program is to submit its report to the grantee and each grantee is to submit the individual reports of each of their affiliate HTCs having an FRP program to the MCHB National Hemophilia Program as a part of their annual grant application.

The burden estimate for this project is as follows: