certificate not less than annually. FDA is not calculating this small fee as cost of doing business because it is less than or equal to the biannual courier costs the registrant incurs for paper submissions.

### IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, *http://www.fda.gov/cvm/guidance/guidance.html*, and *http://www.regulations.gov*.

Dated: July 3, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–15801 Filed 7–10–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0372]**

### Global Harmonization Task Force, Study Groups 1 and 5; 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 final and proposed documents that have been prepared by Study Groups 1 and 5 of the Global Harmonization Task Force (GHTF), respectively. 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 FDA's current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacture of products in the United States.

**DATES:** Submit written or electronic comments on these documents by October 9, 2008. After October 9, 2008, 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 these 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 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the documents.

Submit written comments concerning these documents 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.reguations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

*For information regarding 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 information regarding Study Group 5*:Herbert P. Lerner, GHTF, Study Group 5, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3641.

**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 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 relates to documents that have been developed by two of the Study Groups (1 and 5).

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 guidelines that could help lead to harmonization. As a result of its efforts, this group has developed final document SG1/N44:2008. SG1/N44:2008 (final document) entitled ''Role of Standards'' provides information on the use of standards by a manufacturer when designing a medical device and, subsequently, when demonstrating that the device conforms to relevant essential safety and performance criteria.

Study Group 5 was initially tasked with the responsibility of developing documents on the content and format for clinical investigation reports and on how to conduct and document a clinical evaluation. As a result of its efforts, this group has developed proposed document SG5(PD)/N37:2007. The proposed document SG5(PD)/N37:2007 entitled ''Clinical Investigations'' introduces general principles of clinical investigations of medical devices and general principles when considering the need for a clinical investigation of a medical device. This document primarily addresses the use of clinical investigations to support a marketing authorization application.

### 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. In particular, FDA seeks comments on the

advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacture of products in the United States.

### III. Electronic Access

Persons interested in obtaining a copy of these documents may 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 2, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–15797 Filed 7–10–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0137] (formerly Docket No. 2000D–1383)**

## Guidance for Industry and Food and Drug Administration Staff; Surveillance and Detention Without Physical Examination of Condoms; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Surveillance and Detention Without Physical Examination of Condoms.'' This guidance document provides information to FDA staff and industry about FDA's strategy for addressing further imports of condoms from manufacturers/shippers whose condoms have failed to meet FDA's minimum acceptable quality criteria. The guidance and the strategy are intended to help assure that condoms imported to the United States do not have defects that could compromise their effectiveness and present a health hazard to consumers who rely on condoms for protection from sexually transmitted diseases as well as for contraception.

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled ''Surveillance and Detention Without Physical Examination of Condoms'' 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 240–276–3151. 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** J. Michael Kuchinski, Center for Devices and Radiological Health (HFZ–332), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Consumers use condoms as a barrier to reduce the risk of catching or spreading sexually transmitted diseases and to reduce the risk of unintended pregnancy. Defective condoms present a potentially significant hazard to health for these users.

FDA's Center for Devices and Radiological Health (CDRH) is aware that some foreign manufacturers and shippers of condoms repeatedly attempt to import condoms that fail water leak testing, indicating a level of defects that does not satisfy the acceptable quality criteria described in Compliance Policy Guide 7124.21. To address the issue of firms that repeatedly offer nonconforming condoms for import to the United States, FDA has devised a risk-based tiered process for placing condoms from identified manufacturers/shippers on an import alert, for releasing individual shipments, and for removing condoms from identified manufacturers/shippers from the import alert and consequent potential detention without physical examination. The process involves three levels of import surveillance and detention that may be applied over a 24-month import surveillance cycle.

This final guidance document supersedes the draft guidance entitled ''Surveillance and Detention Without Physical Examination of Condoms,'' which was announced in the **Federal Register** on August 14, 2000 (65 FR 49585). The comment period closed on November 13, 2000.

We received a small number of comments, and FDA has made some changes to the final guidance document based on these comments. One comment indicated that the risk of detention is greater for high-volume manufacturers because they have many shipments and many FDA analyses in a 24-month period and, therefore, a greater cumulative risk of Type 1 statistical sampling error resulting in some shipments failing analyses even though the shipments are acceptable. After analyzing the import data, FDA agrees that, in theory, such sampling errors are possible, although FDA believes that such errors are unlikely to affect most condom manufacturers because they appear to be producing condoms at a defect rate well below the acceptance criteria of the FDA test. Nevertheless, the revised document recognizes the opportunity for