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

manufacturers to present evidence to FDA in support of a reconsideration of their listing on the import alert if they believe for any reason that this listing is inappropriate, including as a result of statistical sampling errors or because previous defective shipments were found during a previously concluded import surveillance cycle.

Another change in the final guidance is that the 24-month surveillance period will start when a firm is placed on Level 1 rather than when a firm is removed from Level 1, as proposed in the draft guidance. This change is being implemented to simplify the process and provide a ''level playing field'' for low-volume firms that export shipments of condoms to the United States less frequently than high-volume firms and therefore generally take a longer time to obtain a number of consecutive passing entries sufficient for removal from the import alert.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Surveillance and Detention Without Physical Examination of Condoms.'' 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

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Surveillance and Detention Without Physical Examination of Condoms,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1139 to identify the guidance you are requesting.

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. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

The information collection recommendations included in this document as part of the strategy for addressing further shipments of condoms from manufacturers/shippers who repeatedly export defective condoms to the United States do not require OMB clearance under the PRA. These collections of information are excepted from the requirements of the PRA under 5 CFR 1320.4(a)(2) and (c). The guidance recommends information to be collected and submitted to FDA ''during the conduct of an administrative action, investigation, or audit involving the agency against specific individuals'' (5 CFR 1320.4(a)(2)) and ''after a case file or equivalent is opened with respect to a particular party'' (5 CFR 1320.4(c)) in order for that specific party to rebut the appearance of adulteration and consequently obtain release of a specific shipment of condoms or removal of specific condoms from listing on Import Alert.

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.

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 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15765 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–0186] (formerly Docket No. 2000D–1384)

Guidance for Industry and Food and Drug Administration Staff; Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves; 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 Surgeons' and/or Patient Examination Gloves.'' This guidance document provides information to FDA staff and industry about FDA's strategy for addressing further imports of surgeons' and patient examination gloves (medical gloves) from manufacturers/shippers whose medical gloves have failed to meet FDA's minimum acceptable quality criteria. The guidance and the strategy are intended to help assure that medical gloves imported to the United States meet FDA's minimum acceptable quality criteria and do not have defects that could compromise their effectiveness and pose a health hazard to healthcare professionals and patients who rely on medical gloves for protection from blood- and fluid-borne pathogens.

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 Surgeons' and/or Patient Examination Gloves'' 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