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period will start when a firm is placed on Level 1 rather than when a firm is removed from Level 1, as proposed in the draft guidance.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

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: Diane Goldsberry, Center for Devices and Radiological Health (HFZ–333), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

SUPPLEMENTARY INFORMATION:

I. Background

Healthcare providers, professionals, and others use surgeons' and/or patient examination gloves (medical gloves) as a barrier against the transmission of blood- and fluid-borne pathogens. Defects in medical gloves, such as holes, can compromise the effectiveness of the glove barrier integrity and pose a potentially significant hazard to the health of users as well as patients.

FDA's Center for Devices and Radiological Health (CDRH) is aware from its import records that some foreign manufacturers and shippers repeatedly attempt to import into the United States medical gloves that fail water leak testing and therefore do not meet the acceptable quality criteria defined in 21 CFR 800.20. To address this situation, FDA has devised a risk-based tiered process for placing medical gloves from identified manufacturers/shippers on an import alert, for releasing individual shipments, and for removing medical gloves from the 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 Surgeons' and/or Patient Examination Gloves,'' which was announced in the **Federal Register** of July 26, 2000 (65 FR 45991). The comment period closed on October 24, 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 medical glove manufacturers because they appear to be producing medical gloves 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 was proposed in the original 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 gloves 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 Surgeons' and/or Patient Examination Gloves.'' 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 Surgeons' and/or Patient Examination Gloves,'' 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 1141 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 medical gloves from manufacturers/shippers who repeatedly export defective medical gloves 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 particular shipment of its medical gloves or removal of its medical gloves 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. E8–15766 Filed 7–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Approaches to Reduce Risk of Transfusion-Transmitted Babesiosis in the United States; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Approaches to Reduce the Risk of Transfusion-Transmitted Babesiosis in the United States.'' The purpose of the public workshop is to discuss the risk and possible approaches to minimize the incidence of transfusion-transmitted babesiosis in the United States. We are convening this workshop at the present time because FDA has observed a recent increase in the number of reports of transfusion-transmitted babesiosis, thus warranting additional discussion to address this blood safety issue. The public workshop will feature presentations and roundtable discussions led by experts from academic institutions, government, and industry.

Date and Time: The public workshop will be held on September 12, 2008, from 7:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Lister Hill Center Auditorium, Bldg. 38A, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov*.

Registration: Mail, fax or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by August 25, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited to 175 attendees. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Babesiosis is a malaria-like illness caused by infection of erythrocytes with protozoan parasites belonging to the genus *Babesia*. Transfusion-transmitted babesiosis is caused by transfusion of blood or blood components collected from donors infected with *Babesia* parasites. During the last 40 years, more than 60 cases of transfusion-transmitted babesiosis have been recognized in the United States. In fiscal years 2006 and 2007, FDA received a total of five reports of fatal transfusion-transmitted babesiosis (primary or contributory cause of death) in the United States.

The public workshop will facilitate a scientific discussion on approaches to reduce the risk of transfusion-transmitted babesiosis in the United States. Topics to be discussed include: (1) Biology, pathogenesis, transmission and epidemiology of babesiosis; (2) risk of *Babesia* infections through transfusion of blood and blood components; (3) laboratory testing to detect *Babesia* infections; and, (4) possible approaches, including donor testing and donor deferral, to reduce the risk of transfusion-transmitted babesiosis while maintaining blood availability and safety.

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*.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: July 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15799 Filed 7–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Committee, Food Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Food Advisory Committee (FAC), Center for Food Safety and Applied Nutrition (CFSAN).

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations received on or before August 11, 2008 will be given first consideration for membership on the Food Advisory Committee. Nominations received after August 11, 2008 will be considered for nomination to the committee should nominees still be needed.

ADDRESSES: All Nominations for membership should be sent electronically to *CV@FDA.HHS.GOV* or by mail to: Advisory Committee Oversight and Management Staff, 5600 Fisher Lane (HF–4), rm. 15A–12, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is Carolyn Jeletic, Center for Food Safety and Applied Nutrition, 301–436–1913, FAX: 301–436–2633, e-mail: