

contractor, or otherwise uses the services of Mr. Freeman, in any capacity during Mr. Freeman's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 355b(a)(b)). If Mr. Freeman provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Freeman during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Freeman for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2012-N-0865 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 3, 2013.

**Melinda K. Plaisier,**

*Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.*

[FR Doc. 2013-10973 Filed 5-7-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0722]

#### **Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components" dated May 2013. The guidance document recognizes the abbreviated donor history questionnaire

and accompanying materials (aDHQ documents), version 1.3 dated December 2012, prepared by the AABB Donor History Task Force, as an acceptable mechanism for collecting blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations for collecting donor history information. The aDHQ documents will provide blood establishments that collect blood and blood components with a specific process for administering questions to frequent donors of blood and blood components to determine their eligibility to donate. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2011.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Tami Belouin, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled "Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components" dated May 2013. The guidance document recognizes the aDHQ documents, version 1.3 dated December 2012, prepared by the AABB Donor History Task Force, as an acceptable mechanism for collecting

blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations. The aDHQ User Brochure defines a frequent donor as a donor who has previously donated two times using the full-length donor history questionnaire, one donation of which occurred within the previous 6 months. The aDHQ documents will provide blood establishments that collect blood and blood components with a specific process for administering questions to frequent donors of blood and blood components to determine their eligibility to donate. The guidance also advises licensed manufacturers who choose to implement the acceptable aDHQ documents on how to report the manufacturing change consisting of the implementation of the aDHQ documents under 21 CFR 601.12.

In the **Federal Register** of October 24, 2011 (76 FR 65735), FDA announced the availability of the draft guidance of the same title dated October 2011. FDA received some comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: Referencing the most current version of the acceptable aDHQ documents, clarifying that the full-length and abbreviated questionnaires are designed to be implemented together, and editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2011.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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 statutes and regulations.

##### **II. 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 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 601.12 and Form FDA 356(h) have been approved under OMB control number 0910-0338; and the collections of information in 21 CFR 640.63 have been approved under OMB control number 0910-0116.

### III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

### IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: May 2, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-10889 Filed 5-7-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

#### Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Microbiology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on June 13, 2013, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

*Contact Person:* Shanika Craig, [Shanika.Craig@fda.hhs.gov](mailto:Shanika.Craig@fda.hhs.gov), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New

Hampshire Ave., Silver Spring, MD 20993, 301-796-6639, Food and Drug Administration, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On June 13, 2013, the committee will discuss and make recommendations regarding the possible reclassification of influenza detection devices, currently regulated as class I. The committee's discussion will involve making recommendations regarding regulatory classification to either confirm class I or reclassify these devices into class II with special controls. The committee will address issues such as device performance and public health impact to determine whether special controls are needed to ensure the safety and effectiveness of these tests through their total product life cycle. The proposed special controls will be discussed to support the possible reclassification.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 4, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the

names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 30, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 31, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Committee Management Staff, at [annmarie.williams@fda.hhs.gov](mailto:annmarie.williams@fda.hhs.gov) or 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 3, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2013-10891 Filed 5-7-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0430]

#### 510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device; Public Meeting; Request for Comments

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the public meeting entitled "510(k) Device