

effects of tobacco. This history and the lack of trust may prevent independent experts from participating in research on tobacco products and therefore may impede the production of data on MRTPs necessary to assess public health impact." The IOM also notes that "the tobacco industry currently lacks the infrastructure and expertise to independently produce the necessary evidence to support an application to market an MRTP."

As a result of these findings, the IOM recommends in its report that "MRTP sponsors should consider use of independent third parties to undertake one or more key functions, including the design and conduct of research, the oversight of specific studies, and the distribution of sponsor funds for research. Such independent third parties should be approved by the FDA in advance of the research."

The IOM report focuses on research to support MRTP applications, but FDA is also interested in information on third-party governance as it relates more generally to industry-sponsored tobacco research. FDA is interested in receiving information on whether some form of third-party governance should be considered for other types of industry-sponsored tobacco product research, including research to support premarket tobacco product applications and other submissions to FDA, as well as research designed to contribute to general knowledge regarding tobacco products.

## II. Request for Comments and Information

As FDA considers how and whether to implement third-party governance of industry-sponsored tobacco product research, we are requesting comments on the IOM's recommendation. We encourage you to submit any available research or evidence to support your comments. FDA specifically requests comments on:

1. What are some potential models of third-party governance of industry-sponsored tobacco product research? What are the strengths and weaknesses of these models?

2. What criteria could FDA use to evaluate any potential model of third-party governance of industry-sponsored tobacco product research?

3. What role would various interested parties (e.g., individual researchers, academic institutions, for-profit and not-for-profit research organizations) play in a third-party governance model of tobacco product research?

4. Who would participate in a third-party governance model? How could a governance model be structured to reduce conflict of interest and bias in

industry-sponsored tobacco product research?

5. What barriers, if any, would have to be overcome to encourage the broader scientific community to participate in a third-party governance model?

6. Are there unique research challenges faced by small manufacturers and how should they be addressed in a third-party governance model?

7. What kinds of tobacco product research could be subject to third-party governance? For example, could it be applied to:

- Product testing?
- Nonclinical studies?
- Studies in human subjects? (e.g., health effects research, behavioral research, abuse liability studies, consumer perception research)

- Computational modeling?
- Postmarket surveillance?

8. What aspects of tobacco product research could be subject to third-party governance? For example, should both the design and conduct of research studies be subject to third-party governance?

9. Are there governance models or other steps FDA can take that are more effective for overseeing research to produce generalizable knowledge, such as establishing better testing/research methods and standards, compared to specific product research?

## III. Submission of 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>.

Dated: March 27, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0051]

### User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications; Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "User Fees and Refunds for Premarket Approval Applications (PMAs) and Device Biologics License Applications (BLAs)." The purpose of this guidance document is to identify the types of PMAs and BLAs subject to device user fees, including supplements and other submissions, as well as those that do not have an associated user fee. The guidance also identifies industry and FDA actions on these submissions that may result in a refund of the fee. The draft of this document was issued on March 16, 2009.

**DATES:** Submit either electronic or written 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 "User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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. Identify comments with the

docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Medical Device User Fee Amendments of 2012 (MDUFA III), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2012, including PMAs and device BLAs. The additional funds obtained from user fees will enable FDA, with the cooperation of industry, to improve the medical device review process to meet certain performance goals and implement improvements for the medical device review process.

**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 user fees and refunds for PMAs and device BLAs. 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. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or <http://www.fda.gov/BiologicsBloodVaccines/RegulatoryInformation/default.htm>. To receive "User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document

number 1681 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This draft 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 part 814 have been approved under OMB control number 0910-0231.

**V. 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>.

Dated: March 27, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2013-07577 Filed 4-1-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-1153]

**Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA To Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food; Extension of Comment Period**

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

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the comment period for the notice entitled "Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA To Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food" that appeared in the **Federal Register** of March 5, 2013 (78 FR 14309). In the

notice, FDA requested comments on the findings and recommendations contained in the Institute of Food Technologists (IFT) report to FDA and the submission of information relevant to improving product tracing. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments by July 3, 2013.

**ADDRESSES:** You may submit comments and information, identified by Docket No. FDA-2012-N-1153, by any of the following methods:

**Electronic Submissions**

Submit electronic comments and information in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments and information.

**Written Submissions**

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and Docket No. FDA-2012-N-1153 for this notice. All comments and information received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments and information, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments and information received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Sherri A. McGarry, Office of Foods, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1212, Silver Spring, MD 20903, 301-796-3851.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of March 5, 2013 (78 FR 14309), FDA published a