

TABLE 2—AREAS OF INTEREST—IN VITRO DIAGNOSTIC DEVICES/TECHNOLOGY—Continued

Focus area	Specific areas of interest
Manufacturing of chemistry devices	Clinical Laboratory Improvement Amendments (CLIA) waived devices, blood collection tubes, fecal occult blood devices.
Manufacturing and development of hematology devices	Hematology analyzers (specific interest in new technology).
Manufacturing and development of coagulation devices	Coagulation assays and controls, platelet aggregators devices, prothrombin time/international normalized ratio meters and assays, D-Dimer analyzers and assays.
Observation of clinical testing in a CLIA high complexity laboratory.	Observation of testing in a clinical testing environment.

B. Site Selection

CDRH will be responsible for all travel expenses associated with the site visits. Therefore, selection of potential facilities will be based on the coordination of CDRH's priorities for staff training and the resources available for this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract to the applicant, that firm must agree to participate in the program and must also have a satisfactory compliance history.

III. Request for Participation

Identify requests for participation with the docket number found in the brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 28, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013-07593 Filed 4-1-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0305]

Possible Role of Independent Third Parties in Industry-Sponsored Tobacco Product Research; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for data, information, and comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a

public docket for interested parties to submit to FDA comments on the Institute of Medicine's (IOM) recommendation regarding third-party governance of industry-sponsored tobacco product research.

DATES: Submit electronic or written comments by September 30, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0305, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Electronic Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper 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-2013-N-0305. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read comments received, go to <http://www.regulations.gov> and insert the docket number, 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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Laila Noory, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373 (choose Option 4), FAX: 240-276-3761, email: CTP.3PGovernance@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act). The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding chapter IX (21 U.S.C. 387 *et seq.*) and grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

FDA expects that tobacco product manufacturers will undertake tobacco product research as part of activities regulated under the Tobacco Control Act, including submission of applications for marketing orders under sections 910 and 911 of the FD&C Act. Section 911 of the FD&C Act requires FDA to issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products (MRTPs). Section 911(l)(2) requires that such regulations or guidance be developed in consultation with the Institute of Medicine (IOM), among others, on the design and conduct of such studies and surveillance. Pursuant to this requirement, the IOM convened a multidisciplinary committee and published a report in December 2011. In the report, entitled "Scientific Standards for Studies on Modified Risk Tobacco Products" (<http://www.iom.edu/Reports/2011/Scientific-Standards-for-Studies-on-Modified-Risk-Tobacco-Products.aspx>), the IOM notes that "governance of research is critical to the production of credible and reliable evidence."

Specifically, the IOM report states "[t]here is profound distrust of the tobacco industry and of research supported by the tobacco industry. This distrust is the direct result of the tobacco industry's history of improperly influencing or manipulating scientific findings and messaging about the health

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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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