your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Hausner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4145, Silver Spring, MD 20993–0002, 301–796–1084.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Considerations for Use of Histopathology and Its Associated Methodologies to Support Biomarker Qualification.'' The FDA Critical Path Initiative identified the discovery, characterization, qualification, and use of biomarkers as important for improving the efficiency and success rate of medical product development. Biomarkers have been broadly applied to describe the following:

- Structural features from the molecular to the anatomic level (*e.g.,* genetic composition, receptor expression patterns, radiographic appearances);
- Biochemical measurements (*e.g.,* serum levels of electrolytes, cardiac troponins); and
- Physiologic organ system function tests (*e.g.,* creatinine clearance, pulmonary function tests, cardiac ejection fraction, electrocardiography).

The type of study reports to be submitted in support of a biomarker qualification will depend upon the proposed context of use and the ultimate goal of the submission. The proposed context of use dictates the depth, extent, and rigor of the supporting data for the biomarker. If a biomarker becomes qualified, analytically valid measurements of it can be relied upon to have a specific and interpretable meaning (*e.g.,* physiologic, toxicologic, pharmacologic, or clinical) in drug development and regulatory decision-making. Industry can then employ the biomarker for the qualified context of use during premarketing drug development, and FDA reviewers can be confident about its qualified context of use without the need to reconfirm its applicability or utility. Accordingly, data supporting qualification of a nonclinical biomarker should be reliable, repeatable, and of assured integrity.

In the **Federal Register** of December 30, 2011 (76 FR 82306), FDA announced the availability of a draft guidance entitled ''Use of Histology in Biomarker Qualification Studies.'' The Agency received several comments from the pharmaceutical industry and others. We have carefully considered the comments and have made the following changes in response to the comments: (1) Changed the title of the guidance to ''Considerations for Use of Histopathology and Its Associated Methodologies to Support Biomarker Qualification''; (2) clarified the scope of the guidance; (3) added more information concerning data used to support biomarker qualification; (4) confirmed and clarified the rationale for assessment of outcomes without knowledge of group assignments in confirmatory studies; and (5) clarified the distinction between biomarker sensitivity and specificity. In addition we have made editorial changes to improve clarity. This guidance finalizes the draft guidance issued in December 2011.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on considerations for the use of histopathology and its associated methodologies to support biomarker qualification. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 this guidance were approved under OMB control numbers 0910–0001 for submissions related to 21 CFR 314, and 0910–0014 for submissions related to 21 CFR 312.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11438 Filed 5–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0514]

Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act.'' This guidance is intended to assist manufacturers of devices subject to section 522 postmarket surveillance orders by providing an overview of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), information on how to fulfill section 522 obligations, and recommendations on the format, content, and review of postmarket surveillance plan submissions.

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: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–D–0514 for ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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.

Submit written requests for single copies of the guidance to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Nicole Jones, Associate Director Program Operations, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4108, Silver Spring, MD 20993–0002, 301–796–6062.

SUPPLEMENTARY INFORMATION:

I. Background

Section 522 of the FD&C Act (21 U.S.C. 360*l*) provides FDA with the authority to require manufacturers to conduct postmarket surveillance of certain class II or class III devices. This guidance is intended to assist manufacturers of devices subject to section 522 postmarket surveillance orders by providing an overview of section 522 of the FD&C Act, information on how to fulfill section 522 obligations, and recommendations on the format, content, and review of postmarket surveillance plan submissions.

FDA issued the draft of this guidance, originally entitled ''Draft Guidance for Industry and Food and Drug Administration Staff; Procedures for Handling Section 522 Postmarket Surveillance Studies,'' on August 16, 2011 (76 FR 50740). The comment period ended on November 14, 2011.

This document supersedes the guidance entitled, ''Guidance for Industry and FDA Staff; Postmarket Surveillance under Section 522 of the Federal Food, Drug, and Cosmetic Act,'' dated April 27, 2006.

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 current thinking of FDA on postmarket surveillance under section 522 of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from 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.* Persons unable to download an electronic copy of ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1754 to identify the guidance you are requesting.

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 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 822 have been approved under 0910–0449.

Dated: May 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11450 Filed 5–13–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1203]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements

AGENCY: Food and Drug Administration, HHS.