burden for this section to be 2,932 hours. The annual burden reflects our estimate to test the tobacco products (*i.e.,* carry out laboratory work). The burden estimate assumes that manufacturers report HPHC quantities in cigarette mainstream smoke according to the two smoking regimens described in the table.

The estimated total annual burden for the reporting of HPHC under section 904(c)(1) of the FD&C Act is 3,847 hours. We do not believe there are any capital costs associated with this collection.

Dated: November 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28787 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1630]

Guidance on Qualification of Biomarker—Galactomannan in Studies of Treatments of Invasive Aspergillosis; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Guidance on Qualification of Biomarker—Galactomannan in Studies of Treatments of Invasive Aspergillosis.'' This guidance provides a qualified context of use (COU) for Galactomannan detection in serum and/or bronchoalveolar lavage (BAL) fluid as the sole microbiological criterion to classify patients as having probable invasive Aspergillosis (IA) for enrollment in clinical trials. This guidance also describes the experimental conditions and constraints for which this biomarker is qualified through the CDER Biomarker Qualification Program. This biomarker can be used by drug developers for the qualified COU in submissions of investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the guidance by January 12, 2016

ADDRESSES: You may submit comment 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–2013–D–1630 for ''Guidance on Qualification of Biomarker—Galactomannan in Studies of Treatments of Invasive Aspergillosis.'' 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.

FOR FURTHER INFORMATION CONTACT: Marianne Noone, Center for Drug Evaluation and Research (Office of Translational Sciences, Immediate Office), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4528, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Guidance on Qualification of Biomarker—Galactomannan in Studies of Treatments of Invasive Aspergillosis.'' In the **Federal Register** of October 27, 2014 (79 FR 63921), FDA

announced the availability of a draft guidance entitled ''Draft Guidance on Qualification of Biomarker—Galactomannan in studies of Treatments of Invasive Aspergillosis.'' The Agency received one comment during the public comment period which was supportive of the qualification of this biomarker. This guidance finalizes the draft guidance issued in October 2014.

This guidance provides qualification recommendations for the use of Galactomannan detection in serum and/or BAL fluid as the sole microbiological criterion to classify patients with hematologic malignancies and recipients of allogeneic hematopoietic stem cell transplants and who also have radiologic evidence suggestive of invasive fungal infection (Ref. 1) as having probable IA for enrollment in clinical trials.

Specifically, this guidance provides the COU for which this biomarker is qualified through the CDER Biomarker Qualification Program. Qualification of this biomarker for this specific COU represents the conclusion that analytically valid measurements of the biomarker can be relied on to have a specific use and interpretable meaning. This biomarker can be used by drug developers for the qualified COU in submission of INDs, NDAs, and BLAs without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker. ''Qualification'' means that the use of this biomarker in the specific COU is not limited to a single, specific drug development program. Making the qualification recommendations widely known and available for use by drug developers will contribute to drug innovation, thus supporting public health.

Innovative and improved Drug Development Tools (DDTs) can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers, clinical outcome assessments, and animal models. Refer to DDTs Qualification Programs at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm* for additional information.

In the **Federal Register** of January 7, 2014 (79 FR 831), FDA announced the availability of a final guidance for industry entitled ''Qualification Process for Drug Development Tools'' that described the process that would be used to qualify DDTs and to make new DDT qualification recommendations available on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* The current guidance is an attachment to that final guidance.

CDER has initiated this formal qualification process to work with developers of these biomarker DDTs to guide them as they refine and evaluate DDTs for use in the regulatory context. Once qualified, biomarker DDTs will be publicly available for use in any drug development program for the qualified COU. As described in the January 2014 guidance, biomarker DDTs should be developed and reviewed using this process. For more information on FDA's DDTs Qualification Programs, refer to the following Web page: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm.*

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 for the use of Galactomannan detection in serum and/or BAL fluid as the sole microbiological criterion to classify patients as having probable IA for enrollment in clinical trials. 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. The 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 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6) have been approved under OMB control numbers 0910–0001 and 0910–0014.

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.*

IV. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov.*

1. De Pauw, B., T. J. Walsh, J. P. Donnelly, et al., ''Revised Definitions of Invasive Fungal Disease from European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and the National Institute of Allergy and Infectious Diseases Mycoses Study Group (EORTC/MSG) Consensus Group,'' *Clinical Infectious Diseases*, 46:12, pp. 1813–1821, 2008.

Dated: November 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28804 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0922]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 17, 2015, the Agency submitted a proposed collection of information entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0789. The approval expires on October 31, 2018. A copy of the supporting statement for this