3. Are the conclusions supported by the data?

4. Are the tables clear and appropriate?

5. Is the document organized appropriately? If not, what improvements are needed?

6. Are you aware of any scientific data reported in governmental publications, databases, peer-reviewed journals, or other sources that should be included within this document?

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 2016–19051 Filed 8–10–16; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0115]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by September 12, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0601. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Manufactured Food Regulatory Program Standards—OMB Control Number 0910–0601—Extension

In the **Federal Register** of July 20, 2006 (71 FR 41221), FDA announced the availability of a draft document entitled ''Manufactured Food Regulatory Program Standards (MFRPS).'' These program standards have since been finalized and updated multiple times. The current standards are the framework that States should use to design and manage their manufactured food programs. The current version expires on September 30, 2016, and FDA is proposing to update and submit for issuance with a new expiration date. The current and proposed versions of the standards are available at the docket number identified in brackets at the heading of this document. Persons with access to the Internet may submit email requests for a single copy of the draft manufactured food standards to *OP-ORA@fda.hhs.gov.* There are 42 State programs enrolled, in which each State may receive up to $300,000 each year for a period of 5 years provided there is significant conformance with the 10 standards.

In the first year of implementing the program standards, the State program conducts a baseline self-assessment to determine if it meets the elements of each standard. The State program should use the worksheets and forms contained in the draft program standards; however, it can use alternate forms that are equivalent. The State program maintains the documents and verifies records required for each standard. The information contained in the documents must be current and fit-for-use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic improvement plan that includes the following: (1) The individual program element or documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

In the **Federal Register** of February 12, 2016 (81 FR 7544), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received two comments. However, these comments did not address the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Respondent | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| State Departments of Agriculture or Health | 42 | 1 | 42 | 376 | 15,792 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden has been calculated as 376 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 10 standards contained in MFRPS. The hours per respondent will change as accounted for in the continuing improvement and self-sufficiency of the program.

Dated: August 8, 2016.

**Jeremy Sharp,**

*Deputy Commissioner for Policy, Planning, Legislation and Analysis.*

[FR Doc. 2016–19165 Filed 8–10–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–D–0971]**

### Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period

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

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

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the document entitled ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry and Food and Drug Administration Staff,'' that appeared in the **Federal Register** of May 13, 2016. In the document, FDA requested comments on FDA's recommendations to assist industry in designing studies to establish the analytical and clinical performance characteristics of infectious disease next generation sequencing-based diagnostic devices for microbial identification and detection of antimicrobial resistance and virulence markers. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the document published May 13, 2016 (81 FR 29869). Submit either electronic or written comments by September 12, 2016.

**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–2016–D–0971 for ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry and Food and Drug Administration Staff.'' 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:** Heike Sichtig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4526, Silver Spring, MD 20993–0002, *Heike.Sichtig@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of May 13, 2016 (81 FR 29869), FDA published a document with a 90-day comment period to request comments on the types of studies the FDA recommends to support a premarket application of Infectious Disease Next Generation (NGS) Sequencing Based Diagnostic