

and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the “Medical Device User Fee Cover Sheet,” is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA’s Center for Devices and Radiological Health and FDA’s Center for Biologics Evaluation and Research to initiate the

administrative screening of new medical device applications and supplemental applications.

The total number of annual responses is based on the average number of cover sheet submissions received by FDA in recent years. The number of received annual responses includes cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates (18 minutes).

In the **Federal Register** of December 28, 2018 (83 FR 67287), FDA published

a 60-day notice requesting public comment on the proposed collection of information. One comment was received.

The comment was generally supportive of the user fee cover sheet for medical devices. However, the comment also noted that there are costs associated with the preparation of the cover sheet. The comment did not suggest specific changes to our cost or hour burden estimates provided in this information collection request. We have not changed our estimates as a result of the comment.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3601 .....	6,379	1	6,379	0.30 (18 minutes) .....	1,914

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 350 hours and a corresponding increase of 1,165 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: July 10, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-15161 Filed 7-16-19; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-N-3662]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses**

**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 August 16, 2019.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0584. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto: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.

**Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—21 CFR Part 866**

*OMB Control Number 0910-0584—Extension*

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro

diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with section 513(a)(1)(B) of the FD&C Act, because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and “other appropriate actions as the Secretary deems necessary” (section 513(a)(1)(B) of the FD&C Act). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on March 22, 2006 (71 FR 14377), establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification was codified in 21 CFR 866.3332, a regulation that describes the new classification for reagents for detection of specific novel influenza A viruses and sets forth the special controls that

help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation refers to the document entitled “Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,” which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents. The guidance recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses

become available from the World Health Organization, National Institutes of Health, and other public health entities, sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g) to determine if any design changes may be necessary.

FDA estimates that one respondent will be affected annually. The respondent will collect this information twice per year; each response is estimated to take 15 hours. This results in a total data collection burden of 30 hours.

The guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

In the **Federal Register** of March 5, 2019 (84 FR 7904), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping regarding reagents for detection of specific novel influenza A viruses .....	1	2	2	15	30

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Manufactures are increasingly adopting in silico methods (computational analysis) for the detection of specific novel Influenza A viruses over traditional laboratory techniques. Therefore, few manufactures are using reagents for detection of specific novel influenza A viruses. Based on these industry trends, we estimate a decrease in the number of total annual records and a corresponding decrease of 270 hours in the total burden since our last OMB approval.

Dated: July 10, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–15160 Filed 7–16–19; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2013–N–0297]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prevention of Salmonella Enteritidis in Shell Eggs During Production; Recordkeeping and Registration Provisions**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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 August 16, 2019.

**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 0910–0660. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

**Prevention of Salmonella Enteritidis in Shell Eggs During Production—Recordkeeping and Registration Provisions—21 CFR 118.10 and 118.11**

*OMB Control Number 0910–0660—Extension*

Shell eggs contaminated with *Salmonella Enteritidis* (SE) are responsible for more than 140,000 illnesses per year. The Public Health Service Act (PHS Act) (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce such regulations as “are necessary to prevent the introduction, transmission,