

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

Section 503B of the FD&C act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Waiver request from electronic submission of product reports.	1	1	1	1 .....	1
Total .....	.....	.....	.....	.....	214

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

Respondents to this collection of information are outsourcing facilities. Based upon our evaluation of the information collection, we have adjusted our estimate downward by 16 hours (from 230 to 214) annually to reflect more recent data. We estimate that each year three outsourcing facilities will submit a product report upon initial registration under section 503B of the FD&C Act. We estimate that twice each year 75 outsourcing facilities will submit a report identifying all human drugs compounded in the facility in the previous 6 months. For the purposes of this estimate, each product's SPL submission is considered a separate product response, and therefore each facility's product report will include multiple product responses. We estimate that each facility will average 53 product responses. We expect each product report will consist of multiple product responses per facility and estimate that preparing and submitting this information electronically may take up to 5 minutes for each initial product response.

Assuming an average of 53 product responses per facility, we estimate that, for semiannual reports, preparing and submitting this information electronically will take 1.5 minutes per product response. Our burden estimate for semiannual product report submissions is lower than for initial product reports because outsourcing facilities can save each product response once initially created and submitted. For subsequent reports, an outsourcing facility may resubmit the same file(s) after changing the RootID and version number (both SPL metadata), effective date (to identify the reporting period), and the number of units produced, along with other data as appropriate, to appropriate values for the reporting period. Furthermore, if a product was not compounded during a particular reporting period, no product response would be sent for that product during that reporting period.

We expect to receive no more than one waiver request from the electronic submission process for initial product reports and semiannual reports, and that

each waiver request will take 60 minutes to prepare and submit.

Dated: June 13, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–13068 Filed 6–16–22; 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 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:** Submit written comments (including recommendations) on the collection of information by July 18, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0584. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601

Landsdown St., North Bethesda, MD 20852, 240–994–7399, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 [of HHS] 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. The guidance document is available on our website at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078583.htm>.

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.

In the **Federal Register** of January 25, 2022 (87 FR 3812), 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 .....	12	2	24	15	360

<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 330 hours and a corresponding increase of 22 records. We attribute this adjustment to an increase in the number of devices of this type being manufactured over the last few years.

Dated: June 13, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2018–N–4042]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining Lists of U.S. Establishments With Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, 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:** Submit written comments (including recommendations) on the collection of information by July 18, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0509. 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](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.

**Establishing and Maintaining Lists of U.S. Establishments With Interest in Exporting CFSAN-Regulated Products**

*OMB Control Number 0910–0509—Extension*

The United States exports a large volume and variety of foods in international trade. Foreign governments often require official certification from the responsible authority of the country of origin about imported foods and establishments involved in their production, storage, or distribution. Some foreign governments establish additional requirements with which exporters are required to comply and ask for additional assurances from the responsible authority. Importing countries may require, and FDA may provide, official certification or assurances for food products in different forms, including certificates that accompany specific products or lists of establishments and products that comply with certain requirements.

To facilitate exports of food subject to importing country listing requirements, FDA has historically provided official certification in the form of country- and product-specific export lists that include establishments and their products when: (1) the establishment has expressed interest in exporting their products to these countries; (2) the establishment and the products are subject to FDA’s jurisdiction; and (3) the establishment can demonstrate that it is in good regulatory standing for the