

U.S. Food and Drug Administration  
Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—21 CFR 866.3332

OMB Control Number 0910-0584  
SUPPORTING STATEMENT

**Terms of Clearance:** None.

**A. Justification**

1. Circumstances Making the Collection of Information Necessary

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on February 3, 2006, establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. In accordance with section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)), FDA codified this classification at [21 CFR 866.3332](#). The regulation refers to the special control guidance document, “[Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Virus](#)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078583.htm>), which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for Novel Influenza A Reagents, including the information collection described above.

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 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR 801 have been approved under OMB control number 0910-0485; and the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120.

2. Purpose and Use of the Information Collection

This guidance document recommends that sponsors obtain and analyze data postmarket 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 WHO, NIH, and other public health entities), sponsors of reagents for detection of specific novel influenza A viruses (in vitro diagnostic (IVD) manufacturers or federal agencies that develop and evaluate novel influenza tests) will collect this information, will compare them with the primer/probe sequences in their devices (laboratory testing as needed) and incorporate the result of these analyses into their Quality Management System (approved under OMB control number 0910-0073), as required by 21 CFR 820.100(a)(1) Corrective and Preventive Action. Further, these analyses will be evaluated against the device design

validation and risk analysis required by 21 CFR 820.30(g), Design Validation, to determine if any design changes may be necessary.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820>

If there is a change in the prevalence of influenza caused by the specific novel influenza A virus that the sponsor's device is intended to detect, compared to the prevalence existing when the premarket clinical studies were conducted, the sponsor will collect data on the clinical performance of their device under the new prevalence conditions.

Changes in prevalence may be obtained from national surveillance reports. The prevalence of infection with the specific novel influenza virus their device is intended to detect may change significantly with time, possibly affecting their device performance. The labeling of their device may need to be revised to reflect the new clinical performance data.

3. Use of Improved Information Technology and Burden Reduction

Companies are free to use whatever forms of information technology may best assist them in utilizing this guidance document. FDA estimates that 95% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

As this is a guidance document, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness. There should be no duplicative information collection as a result of this guidance.

5. Impact on Small Businesses or Other Small Entities

The guidance document offers clinical investigators and sponsors (including small businesses) the possibility of using updated influenza viral sequences available through public health and research organizations such as WHO and NIH and incorporating this information into a process already in place, i.e., the Quality Management System. In vitro diagnostic manufacturers are expected to have a mechanism in place to monitor the performance of their devices to ensure that the device continues to meet its performance specifications over time. This guidance's recommendation for collecting postmarket data under new influenza prevalence conditions is a preventive action taken because of anticipated device failure under new conditions of use. Short forms are not applicable. FDA estimates that 95% of respondents are businesses.

FDA aids small business and manufacturers to comply with applicable statutes and regulations by providing guidance and information through the Division of Industry and Consumer Education (DICE). DICE provides workshops, on-site evaluations and other technical and nonfinancial assistance to small manufacturers. The Division also maintains a toll-free 800 telephone number and a website which firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

This guidance does not set a defined schedule for information collection. FDA expects the sponsor to compare the viral sequence updates with their device primer and probe sequences and incorporate the result of these analysis into their Quality Management System semi-annually (immediately before and immediately after the northern hemisphere influenza season). However, FDA cannot predict when the prevalence of influenza caused by the specific novel influenza A virus will change (as compared to the prevalence existing when the clinical evaluations described in the device premarket submission were conducted), which should lead the sponsor to collect data on the clinical performance of the device under the new prevalence conditions. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of March 5, 2019 (84 FR 7904). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

This ICR does collect personally identifiable information (PII). The PII collected is name, organization, email address, and test scores from taking the training. This information collection has been established as a special control for the class II device type, Novel Influenza A Reagents. This classification permits the legal distribution of this device, and the information collection addressed here plays a significant role in providing a reasonable assurance of the safety and effectiveness of this device and of similar future devices. This involves collecting data on the clinical performance of the device under new prevalence conditions.

FDA further determined this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of individuals.

11. Justification for Sensitive Questions

This information collection does not include any questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The requirements of this guidance impose a minimal burden on industry. Based on market trends, FDA estimates that 1 respondent will be affected annually. Each 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.

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

Table 1.--Estimated Annual Recordkeeping Burden					
Activity	No. of Recordkeepers	No. 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

12b. Annualized Cost Burden Estimate

FDA estimates that cost associated with the information collection, including developing standard operating procedures and recordkeeping for each data collection, is \$645.32. This results in a total cost to industry of \$1,290.64 (\$645.32 multiplied by 2 total annual records).

Type of Respondent	Total Burden Hours	Hourly Wage Rate*	Respondent Costs
Life Scientists	6	\$40.80	\$244.80
Executive Secretaries & Administrative Assistants	5	\$28.56	\$142.80
Regulatory Affairs Manager	4	\$64.43	\$257.72
Total Respondent Costs			\$645.32

\*Approximate hourly wage rate is based on The Regulatory Affairs Professional Society (RAPS), "2016 Scope of Practice & Compensation Report for the Regulatory Profession," p. 11, downloaded from <https://www.raps.org/careers/scope-of-practice-survey> on 11/16/18 and the May 2017 National Industry-Specific Occupational and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics,

executive secretaries and executive administrative assistants, occupation code 43-6011, ([http://www.bls.gov/oes/current/oes\\_nat.htm#43-0000](http://www.bls.gov/oes/current/oes_nat.htm#43-0000)); and life scientists, occupation code 19-1000, ([http://www.bls.gov/oes/current/oes\\_nat.htm#19-0000](http://www.bls.gov/oes/current/oes_nat.htm#19-0000)).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

Because the burden includes recordkeeping only, there are no annualized costs to the Federal Government as a result of the guidance.

15. Explanation for Program Changes or Adjustments

There is a decrease in the estimated number of total annual records and a corresponding decrease of 270 hours in the total estimated burden compared with that identified in the ICR previously approved by OMB. This decrease reflects market trends; in which, manufactures are increasingly adopting *in silico* methods (computational analysis) for the detection of specific novel Influenza A viruses over traditional laboratory techniques. This change is an adjustment; no program changes were made.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.