

United States Food and Drug Administration

GUIDANCE ON REAGENTS FOR DETECTION OF SPECIFIC NOVEL INFLUENZA A
VIRUSES

OMB Control No. 0910-0584 -- EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations and guidance. The information collection was established as a special control for the class II device type, Novel Influenza A Reagents. 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. 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](#)” (March 2006), 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.

We therefore request OMB extension of OMB approval of this collection of information pertaining to guidance that describes the 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 found in insert 21 CFR

Part 866; Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses as discussed in this supporting statement.

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.

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. We are unaware of duplicative information collection.

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

FDA published a 60-day notice for public comment in the *Federal Register* of May 1, 2025 (90 FR 18667). FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Data will be kept private to the extent provided by law.

The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII maintained is name and business contact information. All records are maintained at the sponsor facility. FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the sponsor or FDA do not use name or any other personal identifier to retrieve records from the information collected.

The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Information Collection Activity – 21 CFR Part and Guidance Document Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
21 CFR 866.3332 Reagents for detection of specific novel influenza A viruses and FDA Guidance Document “Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses”					
Postmarket analysis of novel influenza A viral sequences - 866.3332(b)(1) and guidance section 8, Postmarket measures	12	2	24	15	360

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This assessment is based on the fact that no new devices have been cleared under 21 CFR 866.3332 since 2022.

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 \$1,320. This results in a total cost to industry of \$31,680 (\$1,320 multiplied by 24 total annual records).

Type of Respondent	Total Burden Hours	Hourly Wage Rate*	Respondent Costs
Life Scientists	6	\$ 98	\$ 588
Executive Secretaries & Administrative Assistants	5	\$ 44	\$ 220
Regulatory Affairs Manager	4	\$ 128	\$ 512
Total Respondent Costs			\$ 1,320

The estimated wage rate for a Life Scientist is based on The Bureau of Labor Statistics (BLS) hourly wage rate of \$48.81 for a life scientist ([Life Scientists, All Other \(bls.gov\)](https://www.bls.gov), accessed 11-12-24). The hourly wage rate of \$49 assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

The estimated wage rate for a Executive Secretaries & Administrative Assistants is based on The Bureau of Labor Statistics (BLS) hourly wage rate of \$22.12 for an executive secretaries & administrative assistant (Secretaries and Administrative Assistants : Occupational Outlook Handbook: : U.S. Bureau of Labor Statistics (bls.gov)), accessed 11-22-24). The hourly wage rate of \$22 assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

The estimated wage rate for a Regulatory Affairs Manager is based on O*NET OnLine hourly wage rate of \$64.21 for a Regulatory Affairs Manager (11-9199.01 - Regulatory Affairs Managers (onetonline.org)), accessed 11-22-24). The hourly wage rate of \$64 assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

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

The special controls guidance instructs sponsors to document their observations and analysis within their own quality system records as part of maintaining compliance. The annual cost to the Federal Government for headquarters personnel, field investigators, and lab technicians involved in the inspection of records and enforcement of the Quality System regulations at 21 CFR part 820 is accounted for in 0910-0073, where FDA expects that 190 full time equivalent (FTE) positions will be allocated to the inspection of records and enforcement of the Quality System regulations. Because FDA believes that potential cost to the government incurred would occur exclusively in the context of inspections conducted pursuant to the Quality System regulations, FDA is reporting a cost of zero in this supporting statement. Please note that FDA plans to pursue consolidation of 0910-0584 with 0910-0120 when it next seeks extension of that information collection.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.