Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—21 CFR 866.3332
OMB # 0910-0584
SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Abstract

OMB clearance is being sought for an information collection that has been established as a special control for the class II device type, Novel Influenza A Reagents. This classification results from the review of a request from a device sponsor (CDC) for a diagnostic test intended to diagnose influenza subtype H5 (Asian lineage), commonly known as avian flu. 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. Specifically, the information collection asks sponsors to obtain and analyze data postmarket to ensure the continued reliability of the device, given the propensity of influenza viruses to mutate and the potential for changes in disease prevalence. This involves collecting data on the clinical performance of the device under new prevalence conditions if there is a change in prevalence of influenza caused by the specific novel virus that the device is intended to detect, as compared to the prevalence of this virus when the clinical studies described in the 510(k) were conducted.

The information collection described above is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of Novel Influenza A Reagents.

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 360c(f)(2)(C),
http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm110188.htm

FDA published a notice of this classification in 21 CFR 866.3332.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=866

The regulation refers to the special control guidance document, “Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Virus”, 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.
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078583.htm

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

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 (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, 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

This 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 Small Manufacturers, International, and Consumers Assistance (DSMICA). DISMICA 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

Notice was published in the **Federal Register** on October 13, 2009 (74 FR 52493) soliciting comments on this information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d).
http://edocket.access.gpo.gov/2009/pdf/E9-24544.pdf
One comment was received, however it was not PRA related.

FDA consulted with CDC regarding this guidance, including the information collection. CDC was supportive.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection will be conducted by sponsors following FDA regulations for human subject protection.

11. Justification for Sensitive Questions

This information collection does not include any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN1

FD&C Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
513(g)	10	2	20	15	300

[1]There are no capital costs associated with this collection of information.

The requirements of this guidance impose a minimal burden on industry. The FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year, estimated to take 15 hours to complete collection. This results in a total data collection burden of 300 hours.

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.

12b. Cost to Respondents

FDA estimates that cost of developing standard operating procedures (one time cost) and other costs associated with the information collection and record keeping for each data collection is $500 (10 hours of work at $50/Hr.). This results in a total cost to industry of $5000 ($500 multiplied by 10 respondents).

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

There are no annualized costs to the Federal Government as a result of this guidance.

15. Explanation for Program Changes or Adjustments

Although it was reported in ICRAS that the number of responses was 40; this number is incorrect and the correct number of responses is 20.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in item 19 of OMB Form 83-I.