U.S. Food and Drug Administration

Guidance for Industry (GFI): Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

OMB Control No. 0910-0701

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration (FDA, us or we) guidance document entitled "*Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic*." The guidance discusses FDA recommendations on adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic. Because of the potential for high employee absenteeism during an influenza pandemic, and because responsibility to report adverse events during such a pandemic remains in effect, the guidance document is intended to help firms meet adverse event reporting requirements under these circumstances.

Specifically the guidance provides recommendations to respondents on focusing limited resources to certain types of reports. It includes recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The guidance recommends that each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes. The guidance explains that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic should: (1) Maintain documentation of the conditions that prevent them from meeting normal reporting requirements; (2) notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist and when the reporting process is restored; and (3) maintain records to identify what reports have been stored.

We therefore request extension of OMB approval for the information collection provisions found in the above-referenced guidance document.

2. Purpose and Use of the Information Collection

FDA believes the approach described in the guidance will make it possible for firms with postmarketing adverse event reporting responsibilities to focus their limited resources on reports related to critical products indicated for the treatment or prevention of influenza. FDA will continue to receive reports on critical medical products. After pre-pandemic conditions are restored, FDA will also have information to ensure that required reports are submitted as part of our ongoing evaluation of postmarketing adverse events for safety problems.

3. Use of Improved Information Technology and Burden Reduction

Although not specifically addressed in the guidance, we assume that firms will rely on their standard electronic information technology systems to develop and maintain the pandemic influenza COOP recommended in the guidance. We also assume that firms will use standard email technology to notify FDA when normal reporting is not feasible and when the normal reporting processes have been restored.

4. Efforts to Identify Duplication and Use of Similar Information

Upon review of our inventory, as well as other agencies within the Department of Health and Human Services that have public health protection responsibilities where similar information collection might occur, we have found no duplication.

5. Impact on Small Businesses or Other Small Entities

The information collection provisions found in the guidance impose no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection recommended in the guidance reflects existing reporting requirements found in current FDA regulations. We believe the recommendations discussed will help mitigate disruptions in these reports that may occur as a result in high absenteeism during an influenza pandemic.

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

This information collection contains no inconsistency with the guidelines in 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d), we published a 60 day notice requesting public comment in the Federal Register of October 31, 2017 (82 FR 50431). Although one comment from an anonymous source was received, it addressed the efficacy of the influenza immunization program rather than implementation of influenza pandemic preparedness, which is the subject of the guidance and information collection. We did not adjust our burden estimate as a result of the comment.

9. Explanation of Any Payment or Gift to Respondents

No gift or payment is provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

Although we do not anticipate confidentiality issues resulting from the information collection, our regulations provide for the confidentiality of information found in marketing applications under 21 CFR 314.430 and 21 CFR Part 20. In addition, the unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 310(j) of the Federal Food, Drug, and Cosmetic Act.

11. Justification for Sensitive Questions

The information collection contains no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hourly Burden

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

Table 1-- Estimated Annual Reporting Burden[1]

Type of Reporting	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Notify FDA when normal reporting is not feasible	500	1	500	8	4,000

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

Table 2 -- Estimated Annual Recordkeeping Burden[1]

Type of Recordkeeping	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Hours Per Record	Total Hours
Add adverse event report planning to COOP	5,000	1	5,000	50	250,000
Maintain documentation of influenza pandemic conditions and resultant high absenteeism	500	1	500	8	4,000
Maintain records to identify what reports have been stored and when the reporting process was restored	500	1	500	8	4,000
Total					258,000

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

Based on the number of manufacturers that would be covered by the guidance, we estimate 5,000 firms will include the following in a COOP: (1) Instructions for reporting adverse events; and (2) a plan for submitting stored reports that were not submitted within regulatory timeframes. We estimate this activity will require 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not expect or anticipate circumstances surrounding the information collection to occur on an annual basis, we estimate that it would take 8 hours to prepare a submission and use this figure as the basis for an annual estimate.

Concerning the recommendation that firms unable to fulfill normal adverse event reporting requirements maintain documentation of the conditions that prevent them from meeting these requirements; maintain records to identify what adverse event reports have been stored; and when the reporting process is restored, we estimate 500 firms will spend 8 hours engaged in these activities, respectively.

12b. Estimates of Costs

We consider there might be a one-time labor cost associated with preparing or revising a COOP to cover adverse event reporting during an influenza pandemic. Assuming a loaded wage rate of approximately $85 per hour (using wage data for clerical staff, upper- and middle-management, and including overhead costs) and multiply this figure by the number of annual burden hours, we calculate this cost to be $21,930,000.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Assuming FDA would allocate approximately 30 minutes per each submission; multiplying this figure by the number of annual responses; and using an average hourly wage-rate of $48, we calculate the cost to the Federal Government would be $12,000.

15. Explanation for Program Changes or Adjustments

We retain the currently approved burden estimate for the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no such plans for the information collection.

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

Display of the OMB Expiration Date is appropriate and included in the guidance document.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.