

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0098]

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Certifier A. Corbin

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of Potential Data Sources for the Sentinel Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed information collection through a survey designed to identify potential data sources and/or data environments that could participate in the Sentinel Initiative to create a national, electronic distributed system, strengthening FDA's ability to monitor the postmarket performance of a medical product.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All

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comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794. To obtain a copy of the draft survey instrument contact Tomeka Arnett on 301-827-1512.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

Evaluation of Potential Data Sources for the Sentinel Initiative

In September 2005, the Secretary of Health and Human Services (the Secretary) asked FDA to expand its current system for monitoring medical product performance. The Secretary asked FDA to explore the possibility of working in collaboration with multiple healthcare data systems to augment FDA's capability of identifying and evaluating product safety information beyond its existing voluntary reporting systems. Such a step would strengthen FDA's ability, ultimately, to monitor the performance of a product after marketing approval. The Secretary recommended that FDA explore creating a public-private collaboration as a framework for such an effort leveraging increasingly available large, electronic healthcare databases and taking advantage of emerging technologies and building on existing systems and efforts, rather than creating new systems.

In 2006, the Institute of Medicine (IOM) issued a report entitled "The Future of Drug Safety—Promoting and Protecting the Health of the Public."¹ Among other suggestions, this IOM report recommended FDA identify ways to access other health-related databases and create a public-private partnership to support safety and efficacy studies.

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007² (FDAAA). Section 905 of FDAAA calls for the Secretary to develop methods to obtain access to disparate data sources and to establish

¹ Institute of Medicine, "The Future of Drug Safety—Promoting and Protecting the Health of the Public," September 22, 2006, <http://www.iom.edu/>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

² Food and Drug Administration Amendments Act of 2007, Public Law 110–85, was signed into law in September 2007. See Title IX, Section 905.

an active postmarket risk identification and analysis system that links and analyzes healthcare data from multiple sources. The law sets a goal of access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires FDA to work closely with partners from public, academic, and private entities. FDA views the Sentinel Initiative as a mechanism through which this mandate can be carried out.

Consistent with FDA's mission to protect and promote the public health, FDA is embarking on the Sentinel Initiative to create a national, electronic distributed system, strengthening FDA's ability to monitor the post-market performance of a product. As currently envisioned, the Sentinel Initiative will enable FDA to capitalize on the capabilities of multiple, existing data systems (e.g. electronic health record systems and medical claims databases) to augment the agency's current surveillance capabilities. The proposed system will enable queries of distributed data sources quickly and securely for relevant product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be included. Operations will adhere to strict privacy and security safeguards.

The success of this Initiative will depend largely on the content, quality, searchability, and responsiveness of participating data sources and/or data environments. It is essential that FDA understand the strengths and limitations of potential data sources that might be included in the Sentinel Initiative. This survey will be used to collect information from potentially participating data sources and/or environments. The data we are seeking will describe the characteristics of the data available, not personally identifiable information. The findings will help FDA plan for this proposed system and for future work related to the Sentinel Initiative.

This survey will collect information on the scope, content, structure, quality, and timeliness of data; patient population(s), duration of follow up, and capture of care across all settings; availability, experience, and interest of investigators with knowledge of the data in using it for post-market product safety surveillance as well as plans for further data source enhancements; availability, experience, and interest of investigators with knowledge of the data in participating in a distributed data system; and barriers that exist to including each data source in the Sentinel Initiative.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

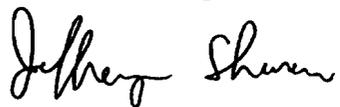
| Activity | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---------------------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| Data Source and/or Environment Survey | 250 | 1 | 250 | 24.5 | 6,125 |

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

FDA estimates that approximately 250 respondents will participate in this voluntary survey. These respondents will consist mostly of other Federal agencies, health plan data sources, health information exchanges, large multi-specialty medical groups and academic medical centers, large hospital systems, pharmacies, medical societies, consumer-oriented Web sites, commercial data sets, research networks, lab data, and registries.

Each respondent will extend approximately 24.5 hours to complete 1 survey for a total of 6,125 hours (250 x 1 x 24.5 = 6,125).

Dated: **FEB 27 2009**
February 27, 2009.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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