OMB No. 0910-0657

Expiration Date: 2/28/2013

INSTRUCTIONS AND BACKGROUND TO ACCOMPANY SURVEY

As part of its Sentinel Initiative, FDA is conducting a survey to get a better understanding of the data sources that may be available as part of a future Sentinel System. FDA has contracted with Booz Allen Hamilton to identify and characterize potential data sources. We are asking data owners to complete the attached survey.

Background on Sentinel:

In May 2008, the Secretary of Health and Human Services and the FDA Commissioner announced the Sentinel Initiative. The Sentinel Initiative is a long-term effort by FDA to create a national electronic system for monitoring product safety. Once developed and implemented, the Sentinel System is intended to augment FDA's existing postmarket (primarily passive) safety surveillance systems and to enable FDA to actively gather information about postmarket safety and performance of FDA-regulated products.

As currently envisioned, the Sentinel System will enable FDA to capitalize on the capabilities of multiple, existing automated healthcare data systems (e.g. electronic health record systems, administrative claims databases, registries, others) to strengthen FDA's current safety surveillance capabilities. The Sentinel System will enable queries of disparate 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 the Sentinel System will be included. Queries would be sent to the appropriate participating data owners, who in turn would, in accordance with existing privacy and security safeguards, evaluate their data and send summary results for Agency review.

For additional background on the Initiative, please see: http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm.

Instructions:

Please complete the attached Excel survey and return your responses to Dorothy Stam at Booz Allen Hamilton by April 30, 2010. Dorothy's email address is stam_dorothy@bah.com.

Please note there are three tabs to complete in the Excel survey.

Who should complete the survey?

All automated healthcare data owners are encouraged to complete the survey. The FDA is particularly interested in automated healthcare data sources that have the technical capability to link exposure of a FDA-regulated product to a health outcome.

What if an organization has more than one source of data?

If your organization has more than one source of data FDA would like your organization to complete a separate survey for each source of data.

What if an organization has limited resources to respond to the survey?

Although FDA encourages each organization to complete the entire survey, partially completed surveys will also be accepted.

What if an organization has additional supporting information to share with FDA?

In addition to collecting survey responses, FDA is interested in collecting any additional supporting information about a given data source that might help FDA better understand the data source, especially as it relates to its potential participation in the Sentinel System.

Information of Interest	Rationale/Importance
Describe capacity for data holder to validate signals via medical chart review	Help FDA determine if the signals that are detected and strengthened in database evaluations can be validated in source documentation as having actually occurred.
Describe strengths and potential limitations of the data source for postmarket surveillance	Help FDA better understand the performance characteristics of the data source from those most familiar with the data
Describe experience in safety signal detection	Assist FDA in better understanding capabilities of potential Sentinel System data sources
Describe available epidemiologic expertise, data management, and programming resources	Inform FDA on the available personnel capable of carrying out evaluations in the potential data source
Provide plans for future data source enhancements	Inform FDA about anticipated changes in data characteristics and structure as they relate to the current status of the data source reflected in the survey response
Describe existing policies and/or processes and agreements that are ordinarily put in place to enable the use of the data for public health purposes	Inform FDA of policy issues that will need to be addressed during the development of the Sentinel System
Describe interest in participating in a distributed data system for postmarket safety surveillance	Assist FDA in better understanding the scope of potential participants in the Sentinel System
Provide letters of support and curriculum vitae from internal and external researchers that describe their experience working with the data source that highlight current uses of the data	Assist FDA in better understanding how these uses relate to potential capabilities and functionalities envisioned within the Sentinel System

Who will see the responses to the survey?

Booz Allen Hamilton has been contracted by the FDA to conduct an evaluation of possible data sources for use in the Sentinel Initiative. They will receive responses and will employ the following procedures to protect confidentiality of information submitted by respondents.

- Respondent information will be accessed on “need to know” basis. Only those individuals responsible for results compilation and analysis will have access to this information
- All contractors with “need to know” access will have signed Non Public Information agreements.
- Respondent Microsoft Excel files will be password protected upon receipt.
- Respondent information will be stored on Booz Allen computers that are protected by Safeboot Encryption as well as Microsoft Windows encryption
- Any paper copies of respondent information will be stored in locked cabinets

- Upon contract close-out, all respondent information will be provided to FDA and contract will erase and destroy all responses.

Booz Allen Hamilton, as a part of the deliverable for this contract, will complete a report detailing the findings from this survey which will be made publicly available on FDA's Sentinel Initiative website. Any information included in any survey responses that is deemed proprietary in nature and is therefore not releasable in accordance with the Freedom of Information Act will be remain confidential in accordance with the Act.

Who should an organization contact if they have questions about the survey?

If questions arise related to the survey, please contact Kayla Garvin at Food and Drug Administration. Kayla's email address is Kayla.Garvin@fda.hhs.gov. She can also be reached by telephone at 301-796-7578.