*The Department specifically requests comments on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 4, 2009.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E9–10622 Filed 5–6–09; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0192]**

### Availability of Information Related to the Sentinel Initiative

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the opening of a docket to receive and to make available to the public reports and other relevant information received by FDA related to the Sentinel Initiative. The goal of the Sentinel Initiative is to develop a system that will ultimately enable FDA to actively monitor the safety of marketed regulated products. The information that will be made available is being developed primarily, but not exclusively, as a result of a series of contracts awarded by FDA to inform the development of the system. The information will be made available in the docket under the docket number at the top of this notice, as well as on FDA's Sentinel Initiative Web page (Sentinel Web page) at *http://www.fda.gov/oc/initiatives/advance/sentinel/*. FDA welcomes interested parties, including individuals, to submit to this docket their views and perspectives on the information included in the docket or on any other aspect of the Sentinel Initiative.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written comments on the information in this docket to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the information.

**FOR FURTHER INFORMATION CONTACT:** Melissa Robb, Office of Critical Path Programs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1512.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

An important part of FDA's mission is to protect public health by monitoring the safety of marketed regulated products. FDA currently has a number of reporting systems in place for learning about and tracking reports of adverse events and product problems associated with the use of FDA-regulated products. However, most of these systems are passive; someone (e.g., a healthcare professional, consumer, pharmaceutical company) must first report such an event or problem to FDA. To augment this mostly passive approach to monitoring postmarket safety, FDA announced in May 2008 the development of a system that would enable FDA to capitalize on the capabilities of multiple existing electronic health care data systems (e.g. electronic health record systems, administrative claims databases, registries) to actively monitor regulated product safety.

As currently envisioned, the system would enable FDA to query large participating data sources quickly and securely for relevant product safety information. FDA would send questions to participating data holders, who in turn would, in accordance with existing privacy and security safeguards, evaluate their data and send summary results to FDA for agency review. This system, which will be developed and implemented in stages, is expected to facilitate the development of active surveillance methodologies related to signal detection, signal strengthening, and signal validation.

To be successful, the system will require the participation of many stakeholders. Since announcing the Sentinel Initiative, FDA has fostered a broad public forum to explore the complexities of creating such a system. Numerous meetings have been held with a variety of stakeholders. Eight contracts have been awarded to explore a variety of topics that will inform the development of the system, and a number of pilot projects are under way that will contribute to answering some of the many technical and policy challenges that need to be addressed. To ensure the broadest possible availability of information related to FDA's Sentinel Initiative and to encourage public participation in the initiative, FDA is announcing the opening of a docket to receive and make available to the public reports and other information received by FDA related to the Sentinel Initiative. FDA is making this information available in the docket listed at the top of this notice, as well as on FDA's Sentinel Web page at *http://www.fda.gov/oc/initiatives/advance/sentinel/*.

FDA is interested in receiving input from interested parties, including individuals, and encourages those parties to submit to this docket relevant views and perspectives on the information included in the docket or on any other aspect of the Sentinel Initiative.

As reports and other relevant information are submitted to the agency, FDA will make them available to the public by placing them in the docket and posting them on the Sentinel Web page. Those persons wishing to provide their views and perspectives are encouraged to send their input to the docket for broad public consideration.

#### II. Documents Being Submitted With This Notice

FDA is making available with this notice the first of a series of documents containing reports and other information related to the Sentinel Initiative. This document contains a report from the Group Health Cooperative Center for Health Studies as a result of the contract awarded on Evaluation of Existing Methods for Safety Signal Identification for the Sentinel Initiative.

#### III. Submission of Input on the Contents of This Docket

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic views and perspectives regarding this information. Submit a single copy of electronic submissions or two paper copies of any mailed submissions, except that individuals may submit one paper copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Electronic comments or submissions will be accepted by FDA only at *http://www.regulations.gov*.

Dated: April 30, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–10555 Filed 5–6–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; Comment Request; NHLBI Health Information Center's Revolving Customer Satisfaction Survey

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* NHLBI Health Information Center's Revolving Customer Satisfaction Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The purpose of this survey is to identify those areas in which services provided by the NHLBI Health Information Center (HIC) to health professionals, patients and their families, and the general public are outstanding and areas where improvements are needed. That information will be used to formulate programs, processes, training, and enhancements to raise the level of customer satisfaction with the services provided by the NHLBI HIC. With subsequent surveys, data will demonstrate whether gains have been made in areas for improvement and if new customer needs must be addressed. *Frequency of Response:* Twice a year. *Affected Public:* Individuals. *Type of Respondents:* Individuals who contact the NHLBI HIC by telephone or e-mail during each 1-month data collection period. The annual reporting burden is as follows: *Estimated Number of Respondents:* 99; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 0.05; and *Estimated Total Annual Burden Hours Requested:* 9.9. The annualized cost to respondents is estimated at: $242.15. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

| Type of respondent | Estimated number of respondents | Annual frequency of response | Average burden hours per response | Estimated total annual burden hours requested |
|---|---|---|---|---|
| General Public | 43 | 2 | 0.05 | 4.3 |
| Private Companies | 14 | 2 | 0.05 | 1.4 |
| Public Sector Groups | 13 | 2 | 0.05 | 1.3 |
| Health Professionals | 29 | 2 | 0.05 | 2.9 |
| Totals | 99 | | | 9.9 |

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Ann M. Taubenheim, Principal Investigator, National Heart, Lung, and Blood Institute, Office of Communications and Legislative Activities, NIH, 31 Center Drive, Building 31, Room 4A10, Bethesda, MD 21045, or call non-toll-free number 301–496–4236 or e-mail your request, including your address, to *taubenha@nhlbi.nih.gov*.

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: April 28, 2009.

**Ann M. Taubenheim,**

*Principal Investigator, NHLBI.*

[FR Doc. E9–10586 Filed 5–6–09; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Novel Inhibitors of Bone Morphogenetic Proteins**

*Description of Technology:* Bone Morphogenetic Proteins (BMPs) are signaling molecules that are central in a variety of biological processes, but were first recognized for their role in inducing bone and cartilage development. Abnormal BMP signaling has been implicated in the pathogenesis of a class of joint disorders known as spondyloarthropathies which includes