collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), 610.40, and 630.40 have been approved under OMB control numbers 0910–0116 and 0910–0795; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

In the **Federal Register** of November 7, 2016 (81 FR 78170), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the notice.

Dated: April 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–08306 Filed 4–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Sentinel Training at the Food and Drug Administration; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Sentinel Training at FDA.'' The purpose of the public workshop is to provide training to understand the kinds of questions that can be asked using health care claims data generally and within the FDA Sentinel System specifically, allowing an understanding of the capabilities of the Sentinel System.

DATES: The public workshop will be held on July 10, 2017, from 10 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Kayla Garvin, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, Rm. 6314, Silver Spring, MD 20993, 301–796–7578, *Kayla.Garvin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Sentinel Initiative began in 2008 as a multiyear effort to create a national electronic system for monitoring the performance of FDA-regulated medical products. The Sentinel Initiative is FDA's response to the Food and Drug Administration Amendments Act of 2007 (FDAAA) requirement that FDA work with public, academic, and private entities to develop a system to obtain information from existing electronic health care data from multiple sources to assess the safety of FDA approved medical products.

The Sentinel System uses a distributed data approach in which Data Partners maintain physical and operational control over electronic health care data in their existing environments. The distributed approach is achieved by using a standardized data structure referred to as the Sentinel Common Data Model. Data Partners transform their data locally in accordance with the Common Data Model, which enables them to execute standardized computer programs that run identically at each Data Partner site. Data Partners are able to review the results of the queries before sending them back to the Sentinel Operations Center. Queries are distributed and results are returned through a secure portal to preserve privacy.

II. Topics for Discussion at the Public Workshop

This full-day seminar, targeting clinical researchers and others without direct experience using health care claims data, will provide an overview of data that are and are not available in the Sentinel Distributed Database, the Sentinel Common Data Model, and a description of the distributed tools available to work with the data. This seminar will help those in attendance understand the kinds of questions that can be asked using health care claims data generally and within the Sentinel System specifically. Attendees will leave with an understanding of the capabilities of the Sentinel System. The Sentinel System can help the public, academia, and private entities better understand potential safety issues associated with FDA-approved medical products. Importantly, users can get responses to their questions in a matter of weeks, as compared to months, or even longer using traditional surveillance methods.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site: *https://www.eventbrite.com/e/sentinel-training-at-food-and-drug-administration-registration-32503315291.* Please provide required contact information for each attendee, including name, title, affiliation, and email.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 9 a.m.

If you need special accommodations due to a disability, please contact Kayla Garvin no later than June 30, 2017.

Streaming Webcast of the public workshop: This public workshop will also be Webcast at: *https://collaboration.fda.gov/sentineltraining2017/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that transcripts will not be available.

Dated: April 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–08302 Filed 4–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1393]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 25, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0233. Also include the FDA docket number found in brackets in the heading of this document.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—21 CFR Part 60—OMB Control Number 0910–0233—Extension

SUPPLEMENTARY INFORMATION: FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting the Drug Price Competition and Patent Term Restoration Act of 1984 and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (USPTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by USPTO based on a statutory formula.

When a patent holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.''

The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness'' as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA or whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petition not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, 20 requests for revision of the regulatory review period have been submitted under § 60.24(a). In years 2013, 2014, and 2015, a total of five requests were submitted under § 60.24(a). During that same time period, there have been no requests under §§ 60.30 and 60.40; however, for purposes of this information collection approval, we are estimating that we may receive one submission annually.

In the **Federal Register** of November 1, 2016 (81 FR 75824), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
60.24(a)	3	1.66	5	100	500
60.30	1	1	1	50	50
60.40	1	1	1	10	10
Total					560

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

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–08325 Filed 4–24–17; 8:45 am]

BILLING CODE 4164–01–P