purity and potency) beyond the manufacturer's labeled expiration date so the replacement of stockpiled product could be deferred. This document, once finalized, will provide guidance to government stakeholders on testing to extend the shelf life (*i.e.,* expiration date) under section 564A(b) of the FD&C Act (21 U.S.C. 360bbb–3a(b)) of stockpiled doxycycline tablets and capsules for public health emergency preparedness and response purposes for an anthrax emergency.

The draft guidance applies to both doxycycline monohydrate and doxycycline hyclate tablets and capsules equivalent to 50 mg and 100 mg of doxycycline that are indicated for PEP or treatment of inhalational anthrax. Where doxycycline is mentioned throughout this guidance, it is meant to include both the hyclate and monohydrate forms of the drug that are indicated for PEP or treatment of inhalational anthrax.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information has been approved under OMB control number 0910–0595.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: April 19, 2017.

Anna K. Abram,

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

[FR Doc. 2017–08326 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–0868]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components for Transfusion

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 (the PRA).

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 0910–0681. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion

OMB Control Number 0910–0681—Extension

The guidance document implements the donor screening recommendations for the FDA-approved serological test systems for the detection of antibodies to *T. cruzi.* The use of the donor screening tests are to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors, including donors of Whole Blood and blood components intended for transfusion. The guidance recommends that establishments that manufacture Whole Blood and blood components intended for transfusion should notify consignees of all previously collected in-date blood and blood components to quarantine and return the blood components to establishments or to destroy them within 3 calendar days after a donor tests repeatedly reactive by a licensed test for *T. cruzi* antibody. When establishments identify a donor who is repeatedly reactive by a licensed test for *T. cruzi* antibodies and for whom there is additional information indicating risk of *T. cruzi* infection, such as testing positive on a licensed supplemental test (when such test is available) or until such test is available, information that the donor or donor's mother resided in an area endemic for Chagas disease (Mexico, Central and South America) or as a result of other medical diagnostic testing of the donor indicating *T. cruzi* infection, we recommend that the establishment notify consignees of all previously distributed blood and blood components collected during the lookback period and, if blood and blood components were transfused, encourage consignees to notify the recipient's physician of record of a possible increased risk of *T. cruzi* infection.

Respondents to this information collection are establishments that manufacture Whole Blood and blood components intended for transfusion. We believe that the information collection provisions in the guidance for establishments to notify consignees and for consignees to notify the recipient's physician of record in the guidance do not create a new burden for respondents and are part of usual and customary business practices. Since the end of January 2007, a number of blood centers representing a large proportion of U.S. blood collections have been testing donors using a licensed assay. We believe these establishments have already developed standard operating procedures for notifying consignees and for the consignees to notify the recipient's physician of record.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the

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.