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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma Cruzi Infection in Whole Blood and Blood Components for Transfusion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) 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 April 4, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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 for Transfusion—(OMB Control Number 0910–0681)—Extension

The guidance implements the donor screening recommendations for the FDA-approved serological test systems for the detection of antibodies to Trypanosoma cruzi (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 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 the consignees to notify the recipient's physician of record.

In the **Federal Register** of August 2, 2013 (78 FR 46954), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 630.6 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

Dated: February 27, 2014.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2014–04776 Filed 3–4–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0225]

Announcement of Center for Biologics Evaluation and Research's Move to the Food and Drug Administration's White Oak Campus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Biologics Evaluation and Research (CBER) will be moving its offices and laboratories from various Rockville and Bethesda, MD, locations to the FDA White Oak campus in Silver Spring, MD. The move will commence on or about May 1, 2014, and will end approximately 8 weeks later, on or about July 1, 2014. During this time persons may continue to send applications and other submissions electronically via the FDA Electronic Submissions Gateway to CBER for review, evaluation, or other handling. However, persons should send submissions on paper or on electronic media (CD, DVD), as well as lot release samples to CBER's new mailing addresses once they take effect. CBER's new mailing addresses, including the dates they take effect, as well as other information concerning CBER's move to the FDA White Oak campus in Silver Spring, MD, will be provided on the FDA Web site at *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm*, as they become available. During the period required for relocation of files, equipment, and Agency personnel, CBER will make every effort to meet its review time frames and minimize any potential

delay. Should delays affecting receipt and review of applications and other submissions occur, we intend to update the FDA Web site as needed.

FOR FURTHER INFORMATION CONTACT: John Reilly, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 *et seq.*) and section 351 of the Public Health Service Act (42 U.S.C. 262), CBER is responsible for receiving, reviewing, evaluating, and taking appropriate actions on a variety of regulated activities, including but not limited to:

(1) Investigational new drug applications and investigational device exemption applications for certain products for which CBER has been assigned responsibility;

(2) Biologics license applications submitted for biological products;

(3) New drug applications, abbreviated new drug applications, premarket approval applications, and premarket notifications for which CBER has been assigned responsibility; and

(4) Protocols and samples submitted for official release (lot release).

In an effort to consolidate, FDA is moving CBER's offices and laboratories from various Rockville and Bethesda, MD, locations to the FDA White Oak campus in Silver Spring, MD. The move will commence on or about May 1, 2014, and will end approximately 8 weeks later, on or about July 1, 2014. During this time, persons may continue to send applications and other submissions electronically via the FDA Electronic Submissions Gateway to CBER for review, evaluation, or other handling. However, persons should send submissions on paper or on electronic media (CD, DVD) (including lot release protocols) to CBER's new mailing addresses once they take effect. CBER's new mailing addresses, including the dates they take effect, as well as other information concerning CBER's move to the FDA White Oak campus in Silver Spring, MD, will be provided on the FDA Web site at *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm* as they become available.

Lot release samples should be sent to the appropriate new mailing address when it takes effect. Please note, however, that because of the relocation of CBER's Sample Custodian (the person(s) responsible for receiving official samples, including lot release samples) to the FDA White Oak campus, CBER will not be able to receive lot release samples during the 2 weeks surrounding this personnel move. This pause will allow us to assure the orderly transfer of lot release samples to the FDA White Oak campus in the weeks immediately before and after this move. Therefore, lot release samples should be shipped to CBER either (1) before the pause, using the current address, or (2) after the pause, using the new address once it takes effect. See the FDA Web site at *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm* for the dates of this pause. We also plan to communicate directly with those manufacturers affected by this temporary interruption in CBER's receipt of lot release samples.

During the period required for relocation of files, equipment, and Agency personnel, CBER will make every effort to meet its review time frames and minimize any potential delay. Should delays affecting receipt and review of applications and other submissions occur, we intend to update the FDA Web site as needed.

II. Comments

Persons who have questions or wish further information concerning CBER's move to the FDA White Oak campus in Silver Spring, MD, may access the FDA Web site at *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm* for more information. CBER intends to update this Web site periodically.

Dated: February 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04810 Filed 3–4–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0430]

Draft Guidance for Industry on Ingredients Declared as Evaporated Cane Juice; Reopening of Comment Period; Request for Comments, Data, and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period; request for comments, data, and information.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft guidance for industry entitled ''Ingredients Declared as Evaporated Cane Juice.'' A notice announcing the availability of the draft guidance was published in the **Federal Register** of October 7, 2009, to advise industry of FDA's view that the common or usual name for the solid or dried form of sugar cane syrup is ''dried cane syrup,'' and that sweeteners derived from sugar cane syrup should not be declared on food labels as ''evaporated cane juice'' because that term falsely suggests the sweeteners are juice. We have not reached a final decision on the common or usual name for this ingredient and are reopening the comment period to request further comments, data, and information about the basic nature and characterizing properties of the ingredient sometimes declared as ''evaporated cane juice,'' how this ingredient is produced, and how it compares with other sweeteners.

DATES: Submit either electronic or written comments by May 5, 2014.

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

FOR FURTHER INFORMATION CONTACT: Daniel Y. Reese, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 7, 2009 (74 FR 51610), we published a notice announcing the availability of a draft guidance for industry entitled ''Ingredients Declared as Evaporated Cane Juice.'' We issued the draft guidance to seek comment on our preliminary thinking regarding the use of the term ''evaporated cane juice'' on food labels to declare the presence of sweeteners derived from sugar cane syrup (''cane syrup''). The draft guidance advised industry of our view that the term ''evaporated cane juice'' is not the common or usual name of any type of sweetener, including sweeteners derived from cane syrup. The draft guidance explained that, because cane