Based on Agency data, we have received no more than 50 submissions since establishing the collection in 2017.

Dated: November 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25364 Filed 11–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4844]

"Ruby Chocolate" Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a temporary permit has been issued to Barry Callebaut U.S.A. LLC (the applicant) to market test a product identified as ''ruby chocolate'' that deviates from the U.S. standards of identity for chocolate products. The temporary permit will allow the applicant to evaluate commercial viability of the product and to collect data on consumer acceptance of the product.

DATES: This permit is effective for 15 months, beginning on the date the applicant introduces or causes introduction of the test product into interstate commerce, but not later than February 20, 2020.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: We are giving notice that we have issued a temporary permit to Barry Callebaut U.S.A. LLC. We are issuing the temporary permit in accordance with 21 CFR 130.17, which addresses temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

The permit covers the interstate market testing of the product identified as ''ruby chocolate.'' The test product deviates from the U.S. standards of identity for chocolates (21 CFR 163.111, 163.123, 163.124, 163.130, 163.135, 163.140, and 163.145).

For the purpose of this permit, ''ruby chocolate'' is the solid or semiplastic food prepared by mixing and grinding cacao fat with one or more of the cacao ingredients (namely, chocolate liquor, breakfast cocoa, cocoa, and lowfat cocoa), citric acid, one or more of optional dairy ingredients, and one or more optional nutritive carbohydrate sweeteners. ''Ruby chocolate'' contains not less than 1.5 percent nonfat cacao solids, not less than 20 percent by weight of cacao fat, not less than 2.5 percent by weight of milk fat, not less than 12 percent by weight of total milk solids, not more than 1.5 percent of emulsifying agents, and not more than 5 percent of whey or whey products. It may also contain other ingredients such as antioxidants approved for food use, spices, natural and artificial flavorings, and other seasonings. However, these other ingredients cannot imitate the flavor of chocolate, milk or butter, berry or another fruit. Additionally, ''ruby chocolate'' contains no added coloring. The test product ''ruby chocolate'' contains the principal ingredients used in most of the current standards for cacao products under 21 CFR part 163; however, it deviates from the current standards of identity for chocolate products in terms of its final composition, taste, and color.

The purpose of the temporary permit is to allow the applicant to market test the product throughout the United States. The permit will allow the applicant to evaluate commercial viability of the product and to collect data on consumer acceptance of the product.

The permit provides for the temporary marketing of approximately 60 million pounds (27,215,540 kilograms) of the test product. The test product will be manufactured at the Barry Callebaut facilities located at Aalstersestraat 122, 9280 Lebbeke, Belgium; 400 Industrial Park Rd., St. Albans, VT 05478; and 1175 Commerce Blvd., American Canyon, CA 94503.

Barry Callebaut U.S.A. LLC will distribute the test product to various manufacturers throughout the United States for further manufacturing and market testing. Each ingredient used in the food must be declared on the label as required by 21 CFR part 101. The permit is effective for 15 months, beginning on the date the applicant introduces or causes the introduction of the test product into interstate commerce, but not later than February 20, 2020.

Dated: November 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25325 Filed 11–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dear Health Care Provider Letters: Improving Communication of Important Safety Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, 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 December 23, 2019.

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 0910–0754. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

OMB Control Number 0910–0754—Extension

This information collection supports recommendations found in the Agency guidance document entitled ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' The guidance provides instruction to industry and FDA staff on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. The guidance is available from our website at: *https://www.fda.gov/media/79793/download.*

The guidance document gives specific instruction on what should and should not be included in DHCP letters. Some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information, and have been unable to communicate it to patients, because the letters' content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes recommendations on consulting with FDA on how to develop a DHCP letter, when to send a letter, what type of letter to send, and how to assess the letter's impact. Based on a review of FDA's Document Archiving, Reporting, and Regulatory Tracking System for 2016—2018, we identified 38 DHCP letters that were sent by 24 distinct sponsors during the 3-year timeframe. We estimate that we will receive approximately 13 DHCP letters annually from approximately 8 application holders. FDA professionals familiar with DHCP letters, and with the recommendations in the guidance, estimate that it should take an application holder approximately 100 hours to prepare and send DHCP letters in accordance with the guidance.

In the **Federal Register** of August 19, 2019 (84 FR 42929), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received expressing the importance of communicating safety information, for which we are appreciative. No other comments were received.

We estimate the annual reporting burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Dear Health Care Provider Letters	8	1.625	13	100	1,300

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

Based on a review of the information collection, we have reduced our burden estimate by 17 respondents with a corresponding decrease in annual hours by 1,200. We attribute the decrease to the effectiveness of the guidance.

Dated: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25333 Filed 11–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Centers for AIDS Research (P30) and Developmental Centers for AIDS Research (P30).

Date: December 16–17, 2019.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Chelsea D. Boyd, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC–9823, Rockville, MD 20852–9834, 240–669–2081, *chelsea.boyd@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 15, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–25306 Filed 11–21–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, November 25, 2019, 11:00 a.m. to November 25, 2019, 4:00 p.m., National Institutes of Health Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852, which was published in the **Federal Register** on November 14, 2019, 84 FR 61920.

This notice is to amend the date of the NIMH HIV/AIDS Review meeting from November 25, 2019, from 11:00 a.m.–4:00 p.m. to December 17, 2019, from 1:00 p.m.–5:00 p.m. The meeting is closed to the public.