

program. The evaluation collects the following information: (1) Demographic Data; (2) Expectations of Fellowship or Training Program; (3) Administration Processes and Support to Fellow or Trainee; (4) FDA Retention and Plans of Fellow or Trainee; (5) Training and Education Completed; and (6) Professional/Research Goals. The purpose of this evaluation is to assess the effectiveness of the program and

feedback from participants to improve the quality of the experience.

(4) To end the program, a non-employee must submit the Exit Check List—Participants in FDA fellowship and traineeship programs may be asked to complete the exit check list to manage the exit process and return of FDA property. The Exit Checklist guides the exit process for the following operations components: (1) Access Key/Pass; (2) Accountable Property; (3)

System Applications inactive; (4) Library Materials; (5) Government Issued Documents (*i.e.*, passports); (6) Personal Identity Verification Card/Badge; (7) Borrowed Records; (8) Employee Records; and (9) Information Technology Accounts.

All exit information will be entered to terminate access to any FDA information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New Non-Employee Data Form	1,220	1	1	0.25 (15 minutes)	305
Proof of Health Insurance	600	1	1	0.25 (15 minutes)	150
Emergency Contact Information	1,220	1	1	0.25 (15 minutes)	305
UFMS Supplier and Site Information for Stipend Payments, Financial Information.	600	1	1	0.25 (15 minutes)	150
CONCUR GOV New Traveler Profile	620	1	1	0.25 (15 minutes)	155
Absence Recording Form	1,220	1	1	0.25 (15 minutes)	305
Personal Custody Property Record	1,220	1	1	0.25 (15 minutes)	305
FDA Health Summary	1,220	1	1	1	1,220
Discovery and Invention Form	1,220	1	1	1	1,220
Training Development Plan	1,220	1	1	1	1,220
Final Project Report	1,220	1	1	1	1,220
Training Request	610	1	1	0.5 (30 minutes)	305
Travel Request	610	1	1	0.5 (30 minutes)	305
LMS Access	1,220	1	1	0.25 (15 minutes)	305
SOP Verification	1,220	1	1	0.25 (15 minutes)	305
Program Evaluation	1,220	1	1	0.5 (30 minutes)	610
Exit Checklist	1,220	1	1	1	1,220
Total	9,605

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

Dated: November 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-25332 Filed 11-21-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2066]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the

PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with certain Freedom of Information Act and Privacy Act requests.

DATES: Submit either electronic or written comments on the collection of information by January 21, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 21, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 21, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-N-2066 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you

must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Certification of Identity; Form FDA 3975

OMB Control Number 0910-0832—Extension

This information collection supports Form FDA 3975 entitled “Certification of Identity,” which is used by FDA to identify an individual requesting a particular record under the Freedom of Information Act (FOIA) and the Privacy Act. The form is available from our website at: <https://www.fda.gov/RegulatoryInformation/FOI/default.htm>, although if an individual requests one, we will send it by mail or email. The form is required only if an individual makes an FOIA request or Privacy Act request for records about himself and has not provided sufficient assurances of identity in the incoming FOIA or Privacy Act request.

The FOIA grants the public a right to access Federal records not normally prepared for public distribution. The Privacy Act grants a right of access to members of the public who seek access to one’s own records that are maintained in an Agency’s system of records (*i.e.* the records are retrieved by that individual’s name or other personal identifier). The statutes overlap, and individuals who request their own records are processed under both statutes. The Agency may need to confirm that the individual making the FOIA or Privacy Act request is indeed the same person named in the Agency records. Respondents to the information collection are asked for certain information including name, citizenship status, social security number, address, date of birth, place of birth, signature, and date of signature.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3975; Certification of Identity	50	1	50	.17 (10 minutes)	8.5

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

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]

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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]

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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 oir_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, PRStaff@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.