TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN: HUMAN FOODS [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
117.201(e); disclosure of food manufacturing facility address.	37,134	1	37,134	0.25 (15 minutes)	9,284

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

TABLE 5—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN: ANIMAL FOOD [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species.	330	10	3,300	0.25 (15 minutes)	825
507.7(e)(1); change labels on products with labels.	1,120	4	4,480	1	4,480
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	974	1	974	1	974
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	373	312	116,376	0.01 (36 seconds)	1,163.76
507.28(b); holding and distribution of human food byproducts for use as animal food.	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					27,841.76

[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 since our last request for OMB approval, we have made slight adjustments to reflect a decrease in third-party disclosure burden associated with animal food. In this submission we provide a cumulative estimate for related disclosure activities that we had previously accounted for separately.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19116 Filed 9–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0897]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 28, 2021, from 10:30 a.m. to 3 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0897. The docket will close on October 27, 2021. Submit either electronic or written comments on this public meeting by October 27, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 27, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 27, 2021. 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.

Comments received on or before October 14, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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–2021–N–0897 for ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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 *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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.'' FDA 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information 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 the 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.govinfo.gov/content/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 *https://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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: She-Chia Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–5343, Fax: 301–847–8533, *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 214383, PEPAXTO (melphalan flufenamide) for injection submitted by Oncopeptides AB, approved under 21 CFR 314.500 (subpart H, accelerated approval regulations), in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.

The committee will hear an update where the confirmatory trial demonstrated a worse overall survival in the melphalan flufenamide treatment arm compared to the control arm. Confirmatory studies are post-marketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. Based on the update provided, the committee will have a general discussion focused on next steps for the product including whether the indication should remain on the market while additional trial(s) are conducted.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 14, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time

requested to make their presentation on or before October 5, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 6, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact She-Chia Chen (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19024 Filed 9–2–21; 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 the extension of a temporary permit issued to Barry Callebaut U.S.A. LLC (the applicant) to market test products (designated as ''ruby chocolate'') that deviate from the U.S. standards of identity for cacao products. The extension allows the applicant to continue to evaluate commercial viability of the product and to collect data on consumer acceptance of the product in support of a petition to establish a standard of identity for ''ruby chocolate.'' We also invite other interested parties to participate in the market test.

DATES: The new expiration date of the permit will be either the effective date of a final rule establishing a standard of identity for ''ruby chocolate'' that may result from the petition or 30 days after denial of the petition.

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; or Carrol Bascus, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In accordance with § 130.17 (21 CFR 130.17), we issued a temporary permit to Barry Callebaut U.S.A. LLC, 600 West Chicago Ave, Suite 860, Chicago, IL 60654, to market test products identified as ''ruby chocolate'' that deviate from the requirements of the standards of identity for cacao products in part 163 (21 CFR part 163) (84 FR 64541, November 22, 2019). We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for cacao products issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate marketing tests of products identified as ''ruby chocolate.'' These test products deviate from the U.S. standards of identity for cacao products (§§ 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 semi-plastic food prepared by mixing and grinding cacao fat with one or more of the cacao ingredients (namely, chocolate liquor, breakfast cocoa, cocoa, and low-fat cocoa), citric acid, one or more of optional nutritive carbohydrate sweeteners. ''Ruby chocolate'' contains not less than 1.5 percent nonfat cacao solids, 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, 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 part 163; however, it deviates from the current standard of identify for chocolate products in terms of its final composition, taste, and color.

On February 19, 2021, the applicant asked us to extend the temporary permit so the applicant could have more time to market test the ''ruby chocolate'' and gain additional consumer acceptance in support of the petition to establish a standard for ''ruby chocolate.'' We find that it is in the interest of consumers to extend the permit for continued market testing of ''ruby chocolate'' to gain additional information on consumer expectations and acceptance. Therefore, under § 130.17(i), we are extending the temporary permit granted to Barry Callebaut U.S.A. LLC for temporary marketing of approximately 60 million pounds (27,215,540 kilograms) of ''ruby chocolate'' to provide continued market testing of the specified amount of product for the applicant on an annual basis. The test products will bear the name ''ruby chocolate.'' The new expiration date of the permit will be either the effective date of a final rule establishing a standard of identity for ''ruby chocolate'' that may result from the petition or 30 days after denial of the petition. All other conditions and terms of this permit remain the same.

In addition, we invite interested persons to participate in the market test under the conditions of the permit, except for the designated area of distribution. Any person who wishes to participate in the extended market test should notify, in writing, the Branch Chief, Product Evaluation Labeling Branch, Division of Food Labeling and Standards, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. The notification must describe the amount to be distributed, the area of distribution, and include the labeling that will be used for the test product (see § 130.17(i)). For information on what to include in the notification to FDA, see § 130.17(c). Test products must be labeled in accordance with 21 CFR part 101.