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]

BILLING CODE 4160–01–P

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

syrup has a standard of identity defined by regulation in 21 CFR 168.130, the common or usual name for the solid or dried form of cane syrup is ''dried cane syrup.'' Additionally, the draft guidance stated that sweeteners derived from cane syrup should not be declared as ''evaporated cane juice'' because such sweeteners are not ''juice'' as defined in 21 CFR 120.1(a). The draft guidance also stated that because sweeteners derived from cane syrup are not juice, they should not be included in the percentage juice declaration on the labels of beverages that are represented to contain fruit or vegetable juice (see 21 CFR 101.30).

We are reopening the comment period to obtain additional data and information to better understand: (1) The basic nature and characterizing properties of the ingredient in question; (2) the method of production of this ingredient; and (3) the difference between this ingredient and other sweeteners made from sugar cane, e.g., molasses, raw sugar, brown sugar, turbinado sugar, muscovado sugar, and demerara sugar.

II. Request for Additional Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

FDA requests comments, including supporting data and other 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 derived from sugar cane. We specifically request comments and supporting data on the following questions:

1. How is ''evaporated cane juice'' manufactured? Specifically, how is its method of manufacture different from that of other sweeteners made from sugar cane (such as cane sugar, cane syrup, etc.)? Is there a uniform industry standard for this ingredient as traded in the marketplace?

2. FDA regulations provide general principles for common or usual names to be used in the labeling of foods. The name must describe the basic nature of the food or its characterizing properties or ingredients. Moreover, the name must be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not encompassed within the same name (§ 102.5(a) (21 CFR 102.5(a))).

a. We noted in the draft guidance that sweeteners derived from sugar cane syrup should not be declared in the ingredient list by names which suggest that the ingredients are juice, such as ''evaporated cane juice.'' Does the name ''evaporated cane juice'' adequately convey the basic nature of the food and its characterizing properties or ingredients, consistent with the principles in § 102.5(a)? Why or why not? How does the name ''evaporated cane juice'' square with the principle that the name of a food may not be confusingly similar to the name of any other food that is not encompassed within the same name, given the significant differences in source and composition between this ingredient and beverages that are regulated as ''juice'' under FDA's juice labeling and juice hazard analysis and critical control point (HACCP) regulations (e.g., orange juice and tomato juice)?

b. There are a number of other sweeteners that are derived from sugar cane (such as raw sugar, cane sugar, cane syrup, demerara sugar, muscovado sugar, turbinado sugar, etc.) and that use the term ''sugar'' or ''syrup'' as a part of their name. How is ''evaporated cane juice'' similar to or different from those other sugars and syrups derived from sugar cane in terms of basic nature and characterizing properties or ingredients? Considering that the ingredient sometimes declared as ''evaporated cane juice'' is also a sweetener derived from sugar cane, what would be the rationale for establishing a common or usual name that identifies this ingredient as a ''juice'' rather than as a ''sugar'' or ''syrup,'' and how would such an approach square with the principle that common or usual names should be uniform and consistent among similar foods? What data and other information support your views on these questions?

3. The draft guidance suggested the alternative name ''dried cane syrup'' for the ingredient sometimes declared as ''evaporated cane juice.'' There was a diversity of views in the comments on the guidance about the suggested name, and FDA would like to better understand the reasoning of the comments that objected to it. Applying the principles for common or usual names in § 102.5, in what way does ''dried cane syrup'' fail to identify or describe this ingredient's basic nature or characterizing properties or ingredients? What information and data support or oppose your view?

After reviewing the comments received, we intend to revise the draft guidance, if appropriate, and issue it in final form, in accordance with FDA's good guidance practice regulations in 21 CFR 10.115.

For a copy of the draft guidance or to view comments submitted in response to the draft guidance, please go to *http://www.regulations.gov* and search for the docket number found in brackets in the heading of this document.

Dated: February 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04802 Filed 3–4–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0157]

Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients With Disorders Affecting the Hematopoietic System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients With Disorders Affecting the Hematopoietic System'' dated March 2014. The guidance document provides recommendations for manufacturers, generally cord blood banks, to apply for licensure of minimally manipulated, unrelated allogeneic placental/umbilical cord blood, for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment. The guidance document is intended to assist manufacturers in obtaining a biologics license. The guidance contains information about the manufacture of minimally manipulated, unrelated allogeneic placental/umbilical cord blood and how to comply with