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 Additionally, the draft guidance stated that sweeteners derived from cane syrup should not be declared as ''evaporated cane juice'' because such sweeteners are not ''juice'' as defined in 21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 The draft guidance also stated that because sweeteners derived from cane syrup are not juice, they should not be included in the percentage juice declaration on the labels of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

applicable regulatory requirements. The guidance announced in this document finalizes the draft guidance of the same title dated June 2013 and supersedes the guidance entitled ''Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications'' dated October 2009.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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

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 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 obtain a biologics license. The guidance contains information about the manufacture of minimally manipulated, unrelated, allogeneic placental/umbilical cord blood and how to comply with applicable regulatory requirements.

In the **Federal Register** of June 17, 2013 (78 FR 36196), FDA announced the availability of the draft guidance of the same title dated June 2013. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. Minor changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2013 and supersedes the guidance entitled ''Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications'' dated October 2009.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Elsewhere in this issue of the **Federal Register**, we also are announcing the availability of another, related guidance entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System.'' That guidance supersedes the document entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications'' dated June 2011.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 201 have been approved under OMB control number 0910–0572; 21 CFR part 211 have been approved under OMB control number 0910–0139; 21 CFR part 600 have been approved under OMB control number 0910–0308; 21 CFR parts 601 and 610, and Form FDA 356h have been approved under OMB control number 0910–0338; and 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04813 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–0490]

Guidance for Industry and Food and Drug Administration Staff: Investigational New Drug 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 and FDA Staff: Investigational New Drug 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