



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Draft Guidance for Industry on Ingredients Declared as Evaporated Cane Juice; Reopening of Comment Period; Request for Comments, Data, and Information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SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft guidance for industry entitled “Ingredients Declared as Evaporated Cane Juice.” A notice announcing the availability of the draft guidance was published in the Federal Register of October 7, 2009, to advise industry of FDA’s view that the common or usual name for the solid or dried form of sugar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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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In the Federal Register of October 7, 2009 (74 FR 51610), we published a notice announcing the availability of a draft guidance for industry entitled “Ingredients Declared as Evaporated Cane Juice.” We issued the draft guidance to seek comment on our preliminary thinking regarding the use of the term “evaporated cane juice” on food labels to declare the presence of sweeteners derived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 The draft guidance advised industry of our view that the term “evaporated cane juice” is not the common or usual name of any type of sweetener, including sweeteners derived from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.