



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0430]

Ingredients Declared as Evaporated Cane Juice; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance entitled "Ingredients Declared as Evaporated Cane Juice." The document advises industry of FDA's view that sweeteners derived from sugar cane, including those derived from sugar cane syrup, should not be declared on food labels as "evaporated cane juice." Instead, such ingredients should be declared as "sugar," preceded by one or more truthful, non-misleading descriptors if the manufacturer so chooses.

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

ADDRESSES: You may submit comments as follows:

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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2009-D-0430 for "Ingredients Declared as Evaporated Cane Juice." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 Division of Dockets Management. 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:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to Food Labeling and Standards Staff/Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, 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

We are announcing the availability of a guidance for industry entitled "Ingredients Declared as Evaporated Cane Juice." We are issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the Federal Register of October 7, 2009 (74 FR 51610), we announced the availability of a draft guidance for industry entitled "Guidance for Industry: Ingredients Declared as Evaporated Cane Juice" and invited comment by December 7, 2009. The draft guidance, which was issued in response to the use of the term "evaporated cane juice" on food labels, stated FDA's view that "evaporated cane juice" is not the common or usual name of any sweetener and that the ingredient in question should instead be declared as "dried cane syrup." In the Federal Register of March 5, 2014 (79 FR 12507), we reopened the comment period until May 5, 2014, and requested 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.

We received numerous comments on the draft guidance, including many that included information about the processing and refining of ingredients made from sugar cane. We have modified the final guidance where appropriate. In addition, we made editorial changes to improve clarity. Based on comments stating that the ingredient sometimes declared as evaporated cane juice is not made from cane syrup as defined in 21 CFR 168.130, FDA is no longer recommending that this ingredient be labeled as "dried cane syrup." Instead, the guidance advises that ingredients currently being declared as "evaporated cane juice," as well as other ingredients that meet the description of "sucrose" in 21 CFR 184.1854, should be declared using the term "sugar," accompanied by a truthful, non-misleading descriptor if the manufacturer so desires. The guidance announced in this notice finalizes the draft guidance dated October 2009.

FDA encourages firms that market sugar cane-derived sweeteners or products that contain a sugar cane-derived sweetener to review the final guidance and consider whether the name under which the sweetener is declared in food labeling accurately describes its basic nature and characterizing properties, as required by the common or usual name regulation (21 CFR 102.5). As explained in the final guidance, our view is that products currently labeled as containing "evaporated cane juice" should be relabeled to use the name "sugar," optionally accompanied by a truthful, non-misleading descriptor to distinguish the ingredient from other cane-based sweeteners. FDA would not object to the use of stickers to make this change until the next regularly scheduled label printing.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web sites listed previously to find the most current version of the guidance.

Dated: May 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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