

for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS-10302 (OMB control number: 0938-1078); *Frequency:* Annually; *Affected Public:* Business and other for-profits and Not-for-profit institutions; *Number of Respondents:* 845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Brijet Coachman at 410-786-7364.)

Dated: May 23, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[CFDA Number: 93.576]

#### Announcement of Award of an Urgent Single-Source Grant to Gulf Coast Jewish Family and Community Services in Clearwater, FL

**AGENCY:** Office of Refugee Resettlement, ACF, HHS.

**ACTION:** Notice of the award of an urgent single-source grant to Gulf Coast Jewish Family and Community Services to provide mental health technical assistance services for refugees.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR) announces the award of an urgent single-source grant in the amount of \$225,000 to Gulf Coast Jewish Family and Community Services (Gulf Coast) in Clearwater, FL to train providers to effectively identify and appropriately serve the mental health needs of arriving refugee populations.

**DATES:** The two-year project period for the award is December 1, 2015 through November 30, 2017.

#### FOR FURTHER INFORMATION CONTACT:

Kenneth Tota, Deputy Director, Office of Refugee Resettlement, 330 C. Street, SW., Washington, DC 20201. Telephone: 202-401-4858. Email: [kenneth.tota@acf.hhs.gov](mailto:kenneth.tota@acf.hhs.gov)

**SUPPLEMENTARY INFORMATION:** In the past few years, ORR has seen an increasing need for mental health services among newly-arrived refugees, particularly those who have suffered torture and extreme trauma due to war and genocide. ORR has received numerous reports of refugees from Bhutan and Burma completing suicide. Bhutanese refugees, in particular, have demonstrated a high incidence of suicide upon arrival to the U.S. This fiscal year the program is seeing a significant increase in resettlement of refugees from the Democratic Republic of Congo and Syria.

Refugees face significant barriers to accessing mental health resources since they are unfamiliar with community mental health systems, speak limited English, and have few financial resources. Health and mental health providers are often overwhelmed by the linguistic and cultural differences that refugees present and respond by saying they are unable to provide services. Currently the provision of standardized mental health screening and culturally appropriate mental health services is one the primary challenges facing the US resettlement program. There is no direct provision of much needed mental health services to refugees in many primary resettlement locations.

Gulf Coast has been a longstanding refugee resettlement program and also has been a grantee under the ORR Survivors of Torture program for the past 15 years. In addition, Gulf Coast has provided technical assistance and mental health services to a national network of refugee service providers and mainstream health and mental health professionals for the past 9 years. Gulf Coast is recognized as the primary refugee mental health technical assistance provider to states without a survivor of torture program. As a result of Gulf Coast's training and technical assistance 6 states applied for and received ORR grants to provide direct services to survivors. They are the only technical assistance provider with expertise in both refugee resettlement and direct services to survivors of torture. They are the only national technical assistance provider with expertise in both refugee resettlement

and direct services to survivors of torture.

Gulf Coast's National Partnership for Community Training (NPCT) has provided technical assistance and training services to ORR grantees and other refugee service providers since 2006.

It is expected that ORR will provide awards to this grantee for a 2-year project period with 12-month budget periods. The grantee will be required to submit applications for noncompetitive awards in the subsequent year during the project period. Future awards will be based on the grantee's performance, the availability of funds, and the best interest of the Federal Government.

**Statutory Authority:** This program is authorized by—

(A) Section 412 (c)(1)(A) of the Immigration and Nationality Act (INA)(8 U.S.C. 1522(c)(1)(A)), as amended, which authorizes the Director "to make grants to, and enter into contracts with, public or private nonprofit agencies for projects specifically designed—[. . .](i) to assist refugees in obtaining the skills that are necessary for economic self-sufficiency, including projects for job training, employment services, day care, professional refresher training, and other recertification services; (ii) to provide training in English where necessary (regardless of whether the refugees are employed or receiving cash or other assistance); and (iii) to provide where specific needs have been shown and recognized by the Director, health (including mental health) services, social services, education and other services."

(B) Refugee Assistance Extension Act of 1986, Pub.L. 99-605, Nov 6, 1986, 100 Stat. 3449.

**Christopher Beach,**

*Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.*

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**BILLING CODE 4184-45-P**

## 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.

[FR Doc. 2016-12402 Filed 5-25-16; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

**AGENCY:** Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to [CARB@hhs.gov](mailto:CARB@hhs.gov).

Registration information is available on the Web site <http://www.hhs.gov/ash/carb/> and must be completed by June 18, 2016; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/ash/carb/> on the Meetings page.

**DATES:** The meeting is scheduled to be held on June 21, 2016, from 10:00 a.m. to 5:00 p.m. ET, and June 22, 2016, from 9:00 a.m. to 4:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the Web site for the Advisory Council at <http://www.hhs.gov/ash/carb/> when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than June 18, 2016; public attendance at the meeting is limited to the available space.

**ADDRESSES:** U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW., Washington, DC 20201.

The meeting also can be accessed through a live webcast on the day of the meeting. For more information, visit <http://www.hhs.gov/ash/carb/>.

**FOR FURTHER INFORMATION CONTACT:** Bruce Gellin, Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 260-6638; email: [CARB@hhs.gov](mailto:CARB@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

On June 21, the public meeting will be dedicated to presentations from federal and non-federal stakeholders surrounding topic areas related to incentives for the development of vaccines, diagnostics, and therapeutics. On June 22, the meeting will focus on the topic of the environment and antibiotic-resistance, in addition to a presentation regarding the new guidance from the Food and Drug Administration for Industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With Guidance for Industry #209." The meeting agenda will be posted on the Advisory Council Web site at <http://www.hhs.gov/ash/carb/> when it has been finalized. All agenda items are tentative and subject to change.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Designated Federal Officer at the address/telephone number listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at <http://www.hhs.gov/ash/carb/>.

Members of the public will have the opportunity to provide comments prior to the Advisory Council meeting by emailing [CARB@hhs.gov](mailto:CARB@hhs.gov). Public