

[fda.hhs.gov](https://www.fda.hhs.gov), 301-796-8398, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/advisory-committees> and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 6, 2021, the committee will discuss and make recommendations on the topic "Medical Device Recalls." Once a medical device is available in the U.S. marketplace and in widespread use, unforeseen problems can sometimes lead to a recall. When a device is defective or potentially harmful, recalling that product—removing it from the market or correcting the problem—is the most effective means for protecting the public. A company may recall a device after discovering a problem on its own, or after FDA raises concerns. In rare cases, FDA may require a company to recall a device. When a device is recalled, FDA reviews the company's strategy for resolving the problem by assessing the relative degree of risk associated with the product and making sure the strategy effectively resolves the problem with the device.

FDA provides transparency and communicates information when the public needs to be alerted to a serious hazard, as well as once the recall has been appropriately resolved. The recommendations provided by the committee will address factors FDA and industry should consider to effectively communicate medical device recall information to patients and the public, including but not limited to content, format, methods used to disseminate the message, and timing of communication. The committee will also consider concerns patients have about changes to their device in response to a recall and will discuss ways patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the healthcare provider and patient decision-making process related to a recalled medical device, including implanted devices.

FDA intends to make background material available to the public no later

than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials will be available at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee>. Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations from the public will be scheduled on October 6, 2021, between approximately 2 p.m. to 3 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 8, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 10, 2021. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the committee may send written submissions to the contact person on or before September 16, 2021.

Virtual Breakout Session: Individuals interested in participating in the virtual breakout scenario discussions will need to sign up to participate on or before September 22, 2021. The signup sheet, as well as, additional information pertaining to the virtual scenario discussions will be available at <https://www.fdalive.com/peac>. Everyone who signs up in advance and provides a valid email address will receive an email at least 2 days prior to the meeting with information on how to access the virtual platform that will host the

virtual breakout scenario discussions. Please note due to limited technology capacity, participation in the virtual breakout scenario discussions will be limited to 150 participants. Once capacity reaches 150 participants, the breakout session will be closed to additional participants. Additional information regarding the virtual breakout scenario discussions will be provided at <https://www.fdalive.com/peac>.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov, or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings. Please be advised that, during the virtual scenario breakout discussions, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-17118 Filed 8-10-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel Clinical Trials & Biomarker Studies in Stroke.

Date: August 18, 2021.

Time: 11:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Virtual Meeting).

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Rockville, MD 20852, (301) 435-6033, rajarams@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 5, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-17102 Filed 8-10-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP-2021-0028]

Receipt of Domestic Interested Party Petition Concerning the Tariff Classification of Dried Onion Products

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of receipt of domestic interested party petition; solicitation of comments.

SUMMARY: U.S. Customs and Border Protection (CBP) has received a petition submitted on behalf of a domestic interested party requesting the reclassification, under the Harmonized Tariff Schedule of the United States (HTSUS), of certain dried onion products. CBP currently classifies the subject dried onion products under subheading 2005.99.20, HTSUS, as onions prepared or preserved otherwise than by vinegar or acetic acid. Petitioner

contends that the proper classification for the subject dried onion products is under subheading 0712.20.20, HTSUS, as dried onion powder not further prepared. This document invites comments with regard to the correctness of the current classification.

DATES: Comments must be received on or before October 12, 2021.

ADDRESSES: You may submit comments, identified by docket number, by the first method listed below:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments via docket number USCBP-2021-0028.

- *Mail:* Due to COVID-19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

Instructions: All submissions received must include the agency name and docket number for this notice of domestic interested party petition concerning the tariff classification of dried onion products. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents, exhibits, or comments received, go to <http://www.regulations.gov>. Due to the relevant COVID-19-related restrictions, CBP has temporarily suspended on-site public inspection of public comments.

FOR FURTHER INFORMATION CONTACT: Tanya Secor, Food, Textiles and Marking Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, at (202) 325-0062 or by email at tanya.j.secor@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION:

Background

A petition has been filed under section 516 of the Tariff Act of 1930, as amended (19 U.S.C. 1516), on behalf of Olam West Coast Inc. (Petitioner or Olam), which is an agri-business and supplier of food, ingredients, and raw materials, based in Fresno, California. Olam manages a wide range of production, processing, and supply of agricultural products in twelve states, with a majority of its operations in California. Olam's largest onion and garlic plant is in Gilroy, California. Olam meets all of the requirements of a domestic interested party set forth in 19 U.S.C. 1516(a)(2) and section 175.3(a) in title 19 of the Code of Federal Regulations (19 CFR 175.3(a)).

In New York Ruling Letter (NY) N265994 (July 9, 2015), NY N261449 (February 20, 2015), NY N257752 (October 24, 2014), and NY M86441

(October 13, 2006), CBP classified various mixtures of onion powder and salt or other ingredients as prepared or preserved onions in subheading 2005.99.20 of the Harmonized Tariff Schedule of the United States (HTSUS), which provides for "Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, not frozen, other than products of heading 2006: Other vegetables and mixtures of vegetables: Other: Onions." Petitioner contends that the proper classification for the onion powder mixtures is dried onion powder in subheading 0712.20.20, HTSUS, which provides for "Dried vegetables, whole, cut, sliced, broken or in powder, but not further prepared: Onions: Powder or flour."

Applicable Legal Principles

Classification under the HTSUS is determined in accordance with the General Rules of Interpretation (GRIs) and, in the absence of special language or context which otherwise requires, by the Additional U.S. Rules of Interpretation (ARIs). GRI 1 provides that the classification of goods shall be determined according to the terms of the headings and any relative section or chapter notes. In the event that the goods cannot be classified solely on the basis of GRI 1, and if the headings and legal notes do not otherwise require, GRIs 2 through 6 may be applied in order. GRI 3(b) applies to mixtures, which are *prima facie*, classifiable under two or more headings and which cannot be classified by reference to GRI 3(a). Pursuant to GRI 3(b), mixtures shall be classified as if they consisted of the material or component which gives them their essential character.

Note 3 to Chapter 7, HTSUS, provides that heading 0712 covers all dried vegetables of the kinds falling in headings 0701 to 0711, excluding certain vegetables but including onions. Note 1(a) to Chapter 20, HTSUS, provides that this chapter does not cover vegetables, fruit or nuts, prepared or preserved by the processes specified in Chapter 7, 8, or 11. Conversely, Note 3 to Chapter 20, HTSUS, provides in pertinent part that heading 2005 covers, as the case may be, only those products of Chapter 7, which have been prepared or preserved by processes other than those referred to in Note 1(a).

The Explanatory Notes (ENs) to the Harmonized Commodity Description and Coding System represent the official interpretation of the tariff at the international level. While neither legally binding nor dispositive, the ENs provide a commentary on the scope of each heading of the HTSUS and are generally indicative of the proper interpretation of