II. Participation

A. Establishment Characteristics

CDER will consider the following establishment characteristics when identifying potential participants for this voluntary QMM Prototype Assessment Protocol Evaluation Program:

- The potential participant is an establishment as defined in 21 CFR 207.1 that registers with FDA under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and manufactures, prepares, propagates, compounds, or processes drugs, or APIs used in such drugs, subject to approval or licensure under section 505 of the FD&C Act or section 351 of the Public Health Service Act, or that are marketed pursuant to section 505G of the FD&C Act without an approved application under section 505 of the FD&C Act (often referred to as over-the-counter (OTC) monograph drug products).
- The establishment has received at least one human drug surveillance inspection.[9]
- The current inspection classification for the establishment at the time of the request to participate is No Action Indicated or Voluntary Action Indicated.
- The establishment manufactures, prepares, propagates, compounds, or processes at least one CDER-regulated drug (API or finished drug product) that is currently in commercial distribution in the United States.
- The establishment is willing to participate in an onsite or hybrid assessment.

B. Requests To Participate

Drug product manufacturers that meet the establishment characteristics described in Section II.A and are interested in participating in the voluntary QMM Prototype Assessment Protocol Evaluation Program should submit a request directly to Conchetta Newton (see **FOR FURTHER INFORMATION CONTACT**). To be considered for this program, a request should include all the following information:

(1) A contact person (name and email).

(2) Manufacturing establishment address.

(3) FDA Establishment Identifier and Data Universal Numbering System Numbers.

(4) A brief description of the business operations (*e.g.,* manufacturing, testing, re/packaging, re/labeling, sterilizing, storing, distributing, or salvaging) conducted at the establishment. Please indicate whether you produce APIs, generic drugs, innovator drugs, OTC drugs, biological drug products, and if you are a contract manufacturing or contract testing organization.

(5) Confirmation that the establishment features the characteristics discussed in Section II.A of this notice.

To be eligible to participate in this 2025 program, establishments should submit a request to participate within the request acceptance period as discussed in the **DATES** section. This applies to all establishments regardless of whether they previously submitted a request to participate in the 2024 QMM Prototype Assessment Protocol Evaluation Program.

C. Selection Process

CDER intends to select participants that reasonably reflect the diversity of the industry. CDER intends to notify each establishment of a decision on their request to participate within 45 days after the close of the request acceptance period as discussed in the **DATES** section when this notice closes. CDER intends to select up to nine volunteer participants for this program.

D. CDER-Participant Interactions

CDER intends to notify participants of their selection and confirm participation. This notification would include information about a virtual orientation session in which CDER would share additional information with participating establishments including the program timelines, milestones, and expectations. Participating establishments would also receive a pre-assessment questionnaire, which provides specific topic areas that would be addressed during the assessment, help to prepare in advance of the assessment, and help determine which personnel would be most appropriate to provide supporting information. CDER intends to provide each establishment with options for dates to schedule the 5-day assessment.

Teams of three assessors would conduct each assessment. The QMM assessment team would be composed of CDER staff not including personnel from FDA's Office of Inspections and Investigations charged with the responsibility of ensuring compliance with current good manufacturing practice. In advance of the assessment, the establishment would receive an agenda to ensure the appropriate people are present at the requested times. The entire leadership team would not need to be present for the full assessment. If necessary, personnel may participate remotely.

Following completion of the assessment, each participating establishment would receive a report that provides, for each practice area: their score, a narrative, areas of strength, and opportunities for improvement. After reviewing the report, participating establishments would meet with the QMM assessment team to discuss any questions or comments they have regarding the report.

In the post-assessment phase of this program, participating establishments will be encouraged to select at least one opportunity to improve from the QMM report and develop an improvement plan with defined goal(s) based on that opportunity. Approximately 3 months after receipt of the QMM report, participating establishments will share their improvement plan with CDER and meet to discuss their plan and path forward. Approximately 6 months after receipt of the QMM report, CDER will schedule a final meeting with the participating establishment to discuss any progress made toward achieving their improvement goal(s). CDER will also solicit feedback from each participating establishment on the assessment, the report, and any suggestions or input they wish to share. This information will help CDER evaluate use of its QMM assessment tool and process to determine whether it enables a meaningful assessment of the establishment's quality management practices and if the feedback provided to the establishment was useful.

Dated: April 16, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–06968 Filed 4–22–25; 8:45 am]

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[9] Inspections conducted by FDA or by Mutual Recognition Agreement partners and classified by FDA fulfill this criterion. We also updated the original characteristic (''The establishment has received at least one human drug surveillance inspection in the prior 5 years,'' as published in 89 FR 4950 at 4951) to remove the 5-year timeframe and expand the number of potential establishments that could be eligible to participate.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0647]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product; EBANGA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that EBANGA (ansuvimab-zykl) for injection, approved on December 21, 2020, manufactured by Ridgeback Biotherapeutics, LP, meets the criteria for a material threat MCM priority review voucher.

FOR FURTHER INFORMATION CONTACT: Andrea Gormley, Counter-Terrorism and Emergency Coordination Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., 2nd Floor, Silver Spring, MD 20993–0002, 301–796–2210 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined EBANGA (ansuvimab-zykl), manufactured by Ridgeback Biotherapeutics, LP, meets the criteria for a material threat MCM priority review voucher. EBANGA was approved on December 21, 2020, for the treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including neonates born to a mother who is RT–PCR positive for *Zaire ebolavirus* infection.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv.* For further information about EBANGA (ansuvimab-zykl) for injection, go to the ''Drugs@FDA'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: April 16, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–06970 Filed 4–22–25; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2025–0013]

Receipt of Domestic Interested Party Petition Concerning the Tariff Classification of Cane Sugar Molasses and Liquid Sugar

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 cane sugar molasses and liquid sugar. CBP currently classifies the subject cane sugar molasses under subheading 1703.10.30, HTSUS, as molasses, and the liquid sugar under subheading 1702.90.40, HTSUS. Petitioner contends that the proper classification for the subject cane sugar molasses and liquid sugar is under subheading 1702.90.10, HTSUS, or subheading 1702.90.20, HTSUS, as ''sugar syrups.'' This document invites comments regarding the correctness of the current classification.

DATES: Comments must be received on or before June 23, 2025.

ADDRESSES: Please submit comments, identified by docket number, by the following method:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments via docket number USCBP–2025–0013.

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 cane sugar molasses and liquid sugar. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents, exhibits, or comments received, go to *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Marie Durane, Food, Textiles and Marking Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, at (202) 325–0984 or by email at *marie.durane@cbp.dhs.gov*.

SUPPLEMENTARY INFORMATION:

Background

A petition was filed under section 516 of the Tariff Act of 1930, as amended (19 U.S.C. 1516), on behalf of the American Sugar Coalition (Petitioner or ASC) and its members. ASC is a national coalition that consists of sugar beet and sugar cane farmers, sugar cane millers, sugar beet processors, and sugar cane refiners, either through their membership in various trade associations, or in their individual capacity. Members of the ASC individually manufacture, produce, or wholesale raw and refined sugar in the United States, and Petitioner represents that they produce over 95 percent of all raw and refined sugar in the United States. ASC meets all 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) N309706 (March 10, 2020), CBP classified the product described as refiner's molasses in subheading 1703.10.3000, Harmonized Tariff Schedule of the United States Annotated (HTSUSA),[1] which provides for ''Molasses resulting from the extraction or refining of sugar: Cane Molasses: Imported for (a) the commercial extraction of sugar or (b) human consumption.'' In NY N324972 (June 24, 2022), CBP classified liquid sugar in subheading 1702.90.4000, HTSUSA, which provides for ''Other sugars, including chemically pure lactose, maltose, glucose and fructose, in solid form; sugar syrups not containing added flavoring or coloring matter; artificial honey, whether or not mixed with natural honey; caramel: Other, including invert sugar and other sugar and sugar syrup blends containing in the dry state 50 percent by weight of fructose: Derived from sugar cane or sugar beets: Other: Other.''

[1] Please note that when referencing a heading or subheading up to the 8-digit level of the Harmonized Tariff Schedule of the United States, CBP cites to the Harmonized Tariff Schedule of the United States or ''HTSUS.'' When referencing a 10-digit subheading level of the Harmonized Tariff Schedule of the United States, CBP cites to the Harmonized Tariff Schedule of the United States Annotated or ''HTSUSA,'' which is used for statistical reporting purposes.