DATES: Approval is withdrawn as of December 12, 2019.

FOR FURTHER INFORMATION CONTACT: Sana F. Hussain, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: Haemonetics Manufacturing, Inc., 400 Wood Rd., Braintree, MA 02184, has requested that FDA withdraw approval of ANDA BA 710497/0, pursuant to § 314.150(c) (21 CFR 314.150(c)), because the drug is no longer being marketed. By its request, Haemonetics Manufacturing, Inc., has also waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of the application listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 12, 2019. Introduction or delivery for introduction into interstate commerce for products without an approved new drug application or ANDA violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). The drug product that is listed in the table above that is in inventory on December 12, 2019 may continue to be dispensed until the inventory has been depleted or the drug product has reached its expiration date or otherwise becomes violative, whichever occurs first.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2019–0042]

Commercial Customs Operations Advisory Committee (COAC)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Wednesday, December 4, 2019, in Washington, DC. The meeting will be open to the public to attend either in person or via webinar.

DATES: The COAC will meet on Wednesday, December 4, 2019, from 1:00 p.m. to 5:00 p.m. EST. Please note that the meeting may close early if the committee has completed its business. Comments must be submitted in writing no later than December 3, 2019.

ADDRESSES: The meeting will be held at the Ronald Reagan Building, International Trade Center-Horizon Ballroom, 1300 Pennsylvania Ave. NW, Washington, DC 20229. For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection (CBP), at (202) 344–1440 as soon as possible.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health Center for Scientific Review; Notice of Closed Meetings

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

The meetings 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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Interventions and Mechanisms for Addiction.

Date: December 2, 2019.
Time: 10:00 a.m. to 12:00 p.m.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (boulaym@nih.gov).

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR/STTR).

Date: December 3, 2019.
Time: 10:00 a.m. to 5:00 p.m.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (belangerm@nih.gov).

Name of Committee: Center for Scientific Review Special Emphasis Panel; Lasker Clinical Research Scholars Program (S2/R00 Clinical Trial Optional).

Date: December 3, 2019.
Time: 12:00 p.m. to 6:00 p.m.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301–435–2365, aitouchea@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurodevelopmental and Neurodegenerative Disorders.

Date: December 3, 2019.
Time: 12:00 p.m. to 6:00 p.m.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, bhagavas@csr.nih.gov.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

Pre-Registration: Meeting participants may attend either in person or via webinar after pre-registering using one of the methods indicated below:

For members of the public who plan to attend the meeting in person, please register by 5:00 p.m. EST on December 3, 2019, either: online at https://teregistration.cbp.gov/index.asp?w=169; by email to tradeevents@cbp.dhs.gov; or by fax to (202) 325–4290. You must register prior to the meeting in order to attend the meeting in person.

For CBP personnel who plan to attend in-person, please register online by 5:00 p.m. EST December 3, 2019, at https://teregistration.cbp.gov/index.asp?w=171.

For members of the public who plan to participate via webinar, please register online at https://teregistration.cbp.gov/index.asp?w=170 by 5:00 p.m. EST on December 3, 2019.

Please feel free to share this information with other interested members of your organization or association.

Members of the public who are pre-registered to attend and later need to cancel, please do so by December 3, 2019, utilizing the following links: https://teregistration.cbp.gov/cancel.asp?w=169 to cancel an in-person registration; or https://teregistration.cbp.gov/cancel.asp?w=170 to cancel a webinar registration. For CBP personnel who are registered to attend in-person and later need to cancel, please do so by utilizing the following link: https://teregistration.cbp.gov/cancel.asp?w=171.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

Comments must be submitted in writing no later than December 3, 2019, and must be identified by Docket No. USCBP–2019–0042, and may be submitted by one (1) of the following methods:

- Email: tradeevents@cbp.dhs.gov. Include the docket number in the subject line of the message.
- Fax: (202) 325–4290, Attention Florence Constant-Gibson.
- Mail: Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3SA, Washington, DC 20229.

Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number (USCBP–2019–0042) for this action. Comments received will be posted without alteration at http://www.regulations.gov. Please do not submit personal information to this docket.

Docket: For access to the docket or to read background documents or comments, go to http://www.regulations.gov and search for Docket Number USCBP–2019–0042. To submit a comment, click the “Comment Now!” button located on the top-right hand side of the docket page.

There will be multiple public comment periods held during the meeting on December 4, 2019. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page, http://www.cbp.gov/trade/stakeholder-engagement/coac.

Agenda

The COAC will hear from the current subcommittees on the topics listed below and then will review, deliberate, provide observations, and formulate recommendations on how to proceed:

1. The Next Generation Facilitation Subcommittee will provide an update on the One U.S. Government Working Group’s progress and an overview of the recent two-day meeting, during which the working group discussed the Global Business Identifier and working group priorities. There will be a subcommittee update on the progress of the Unified Entry Processes Working Group’s development of an operational framework and the mapping of deficiencies in the current entry process. The subcommittee will discuss progress on the Emerging Technologies Working Group’s various initiatives, including the recent completion of the Intellectual Property Rights Blockchain Proof of Concept testing and follow-up assessment. Finally, the subcommittee will provide an update on the efforts of the E-Commerce Working Group’s projects and pilots.

2. The Secure Trade Lanes Subcommittee will provide updates on the Trusted Trader Working Group’s activities. They will also provide an analysis of the In-Bond processes with a view to areas that are being developed for greater efficiency. The newly launched Export Modernization Working Group will provide updates regarding categorizing issues with export handling and identification of export data elements and opportunities for export process efficiencies. The Export Modernization Working Group may also submit recommendations for COAC’s consideration. The subcommittee will report on the planned scope of work to be addressed by the newly formed Remote and Autonomous Cargo Processing Working Group.

3. The Rapid Response Subcommittee will provide an update regarding the newly formed Broker Continuing Education Taskforce and their goal to evaluate a continuing education framework for licensed customs brokers.

4. The Intelligent Enforcement Subcommittee will discuss their progress and activities, and they may also submit recommendations from the working groups under their jurisdiction for COAC’s consideration. There will be updates from the following: the recently launched Intellectual Property Rights Working Group, which encompasses the visions of the 21st Century Customs Framework; the Anti-Dumping and Countervailing Duties (AD/CVD) Working Group (reporting on its efforts to discuss the AD/CVD Redesign and Date of Duty Calculation); the Bond Working Group (reporting on risk-based bonding and bond sufficiency); and, the Forced Labor Working Group, which was previously on hiatus (reporting on new topics).


Dated: November 5, 2019.

Valarie M. Neuhart,
Acting Executive Director, Office of Trade Relations.