OMB control number 0910–0340. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Format and Content Requirements for Over-the-Counter Drug Product Labeling—21 CFR Part 201

OMB Control Number 0910–0340—Extension

This information collection supports FDA regulations at § 201.66 (21 CFR 201.66), which establish standardized content and format requirements for the labeling of all marketed over-the-counter (OTC) drug products. The regulations set forth the content and format requirements for the Drug Facts portion of labels on OTC drug products. These regulations require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features.

Currently marketed OTC drug products are already required to comply with these labeling requirements and will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Labeling modifications already required to be in Drug Facts format are ''usual and customary'' as part of routine redesign practice, thus they do not create additional burden within the meaning of the PRA.

Therefore, burden for this information collection is that which is necessary to comply with the labeling requirements in § 201.66, applicable to new OTC drug products and OTC sunscreen drug products introduced to the marketplace under new drug applications, abbreviated new drug applications, or an OTC drug monograph. New OTC drug products must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

Based on our electronic drug registration and listing database, we estimate that approximately 10,463 new OTC drug product stock keeping units (SKUs) are introduced to the marketplace each year. We estimate that these SKUs are marketed by 1,416 manufacturers. We estimate that the preparation of labeling for new OTC drug products requires 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is 94,296 hours.

All currently marketed sunscreen products are required to comply with the Drug Facts labeling requirements in § 201.66, so they will incur no further burden under the information collection provisions in the regulation. However, a new OTC sunscreen drug product, like any new OTC drug product, will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. We estimate, based on our electronic drug registration and listing database, that 5,253 new SKUs of OTC sunscreen drug products will be marketed each year. We estimate that these 5,253 SKUs will be marketed by 294 manufacturers. We estimate that 12 hours will be spent on each label. This is reflected in table 1, row 1.

When determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). We receive very few requests for exemptions or deferrals. We also estimate that a request for deferral or exemption requires 24 hours to complete. This is reflected in table 1, row 2.

In the **Federal Register** of June 19, 2019 (84 FR 28555), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received from a trade organization representing nurse practitioners. The comment advocated revising FDA regulations to provide for provider-neutral language in Agency regulations but acknowledged its use in current Agency guidance. We appreciate this comment, but we decline to adopt the suggestion at this time.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
§ 201.66(c) and (d) for new OTC drug products	855	9.19	7,858	12	94,296
§ 201.66(e)	1	1	1	24	24
Total					94,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 82,797 hours and a corresponding increase of 6,898 disclosures. This increase corresponds with data obtained from our database.

Dated: October 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24509 Filed 11–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4777]

Haemonetics Manufacturing, Inc.; Withdrawal of Approval of Abbreviated New Drug Application of Anticoagulant Citrate Dextrose Solution A, USP

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) BA 710497/0 for Anticoagulant Citrate Dextrose Solution A, USP (ACD–A), In Plastic Bags, held by Haemonetics Manufacturing, Inc. Haemonetics Manufacturing, Inc., requested in writing that the Agency's approval of the application be withdrawn because the drug is no longer being marketed and has waived its opportunity for a hearing.

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.

Application No.	Proprietary name
ANDA BA 710497/0 ...	Anticoagulant Citrate Dextrose Solution A, USP (ACD–A) In Plastic Bags.

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.

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24527 Filed 11–8–19; 8:45 am]

BILLING CODE 4164–01–P

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.

Agenda: To review and evaluate grant applications.

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, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, *boulaymg@csr.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.

Agenda: To review and evaluate grant applications.

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, Rm. 6188, MSC 7804, Bethesda, MD 20892, 301–435–1267, *belangerm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Lasker Clinical Research Scholars Program (Si2/R00 Clinical Trial Optional).

Date: December 3, 2019.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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@csr.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.

Agenda: To review and evaluate grant applications.

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*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 4, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24466 Filed 11–8–19; 8:45 am]

BILLING CODE 4140–01–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.

FOR FURTHER INFORMATION CONTACT: Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229; telephone (202) 344–1440; facsimile (202) 325–4290; or Ms. Valarie M. Neuhart, Acting Executive Director