DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0380]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 12, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—21 CFR Part 3

OMB Control Number 0910–0523—Extension

This regulation relates to Agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product. The second purpose of this regulation is to enhance the efficiency of Agency management and operations by providing procedures for classifying and determining which Agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which Agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products and combination products. The respondents will be businesses or other for-profit organizations.

In the **Federal Register** of July 17, 2019 (84 FR 34188), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3	61	1	61	24	1,464

[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 decrease of 552 hours and a corresponding decrease of 23 responses/records. This adjustment is based on the number of submissions we received since the last OMB approval.

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24513 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–2013–N–0823]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by December 12, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the

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.