patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before May 9, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

David C. Shonka,

Acting General Counsel.

[FR Doc. 2018–07127 Filed 4–6–18; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1069]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 May 9, 2018.

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 0910–0052. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Blood Establishment Registration and Product Listing, Form FDA 2830—21 CFR part 607 OMB Control Number 0910–0052—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, places of business, and all such establishments, among other information, and must submit a list of all drug and all device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution, among other information. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a), requires, in part, that owners or operators of certain establishments that engage in the manufacture of blood products register and submit a list of every blood product in commercial distribution.

Section 607.21 requires the owner or operator of an establishments entering into the manufacturing of blood products to register the establishment within 5 days after beginning such operation and to submit a list of every blood product in commercial distribution at the time. If the owner or operator of the establishment has not previously entered into such operation for which a license is required, registration must follow within 5 days after the submission of a biologics license application. In addition, owners or operators of all establishments so engaged must register annually between October 1 and December 31 and update their blood product listing every June and December.

Section 607.22(a) requires, in part, that initial and subsequent registrations and product listings be submitted electronically through the Blood Establishment Registration and Product Listing system or any future superseding electronic system.

Section 607.22(b) requires, in part, that requests for a waiver of the requirements of § 607.22 be submitted in writing and include the specific reasons why electronic submission is not reasonable for the registrant.

Section 607.22(c) provides that if FDA grants the waiver request, FDA may limit its duration and will specify the terms of the waiver and provide information on how to submit establishment registration, drug listings, other information, and updates, as applicable (*e.g.,* Form FDA 2830).

Section 607.25 sets forth the information required for establishment registration and blood product listing.

Section 607.26 requires, in part, that certain changes, such as ownership or location changes, be submitted to FDA electronically as an amendment to establishment registration within 5 calendar days of such changes using the FDA Blood Establishment Registration and Product Listing system, or any future superseding electronic system.

Section 607.30(a), in part, sets forth the information required from owners or operators of establishments when they update their blood product listing information in June and December of each year (at a minimum).

Section 607.31 requires that certain additional blood product listing information be provided upon request by FDA.

Section 607.40 requires, in part, that certain foreign blood product establishments comply with the establishment registration and blood product listing information requirements in part 607, subpart B (§§ 607.20 through 607.39, 607.40(a) and (b)), and provide the name and address of the establishment and the name of the individual responsible for submitting establishment registration and blood product listing information (§ 607.40(c))

as well as the name, address, and phone number of its U.S. agent (§ 607.40(d)).

This information assists FDA in its inspections of facilities, among other uses, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply.

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for registered blood product establishments.

FDA estimates the burden of this collection of information based upon information obtained from the database of FDA's Center for Biologics Evaluation and Research and FDA experience with the blood establishment registration and product listing requirements.

In the **Federal Register** of December 26, 2017 (82 FR 61013), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Activity/form FDA 2830	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
607.20(a), 607.21, 607.22, 607.25, and 607.40.	Initial Registration.	115	1	115	1	115
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40.	Annual Registration.	2,612	1	2,612	0.5 (30 minutes)	1,306
607.21, 607.25, 607.30(a), 607.31, and 607.40.	Product Listing Update.	200	1	200	0.25 (15 minutes)	50
607.22(b)	Waiver Requests	25		25	1	25
Total						1,496

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

The burden for this information collection has changed since the last OMB approval. Because of a slight increase in the number of initial registrations and product listing updates FDA has received during the past 3 years, we have increased our reporting burden estimate.

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07145 Filed 4–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0545]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 May 9, 2018.

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 0910–0256. 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.

Infant Formula Requirements—21 CFR parts 106 and 107

OMB Control Number 0910–0256—Extension

This information collection supports FDA regulations regarding infant formula requirements. Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). The purpose of the labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately. The regulations for infant formula requirements are codified in 21 CFR parts 106 and 107.

To assist respondents with applicable reporting provisions found in the regulations, we have developed an electronic Form FDA 3978 that allows infant formula manufacturers to electronically submit reports and notifications in a standardized format. Form FDA 3978 prompts respondents to include information in a standardized format and helps respondents organize submissions to include only the information needed for our review. Draft screenshots of Form FDA 3978 and instructions are available at *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.* Form FDA 3978 was deployed in 2017 as a pilot by FDA and, while informal feedback regarding its use has been favorable, we continue to invite comment. If manufacturers prefer, however, FDA continues to accept paper submissions.