4164-01-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

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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 his or her name, place of business, and all such establishments with the Secretary of Health and Human Services on or before December 31 of each year. He or she must also submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. 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), in brief, requires owners or operators of certain establishments that engage in the manufacture of blood products to register and to submit a list of every blood product in commercial distribution.

Section 607.21, in brief, requires the owners or operators of establishments entering into the manufacturing of blood products to register 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 November 15 and December 31 and update their blood product listing every June and December.

Section 607.22 requires the use of Form FDA 2830, Blood Establishment Registration and Product Listing, for initial registration, for subsequent annual registration, and for blood product listing information.

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

Section 607.26, in brief, requires certain changes to be submitted on FDA Form 2830 as an amendment to establishment registration within 5 days of such changes.

Section 607.30(a), in brief, sets forth the information required from owners or operators of establishments when updating their blood product listing information every June and December, or at the discretion of the registrant at the time the change occurs.

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

Section 607.40, in brief, requires certain foreign blood product establishments to comply with the establishment registration and blood product listing information requirements discussed earlier in this document and to provide the name and address of the establishment and the name of the individual responsible for submitting the establishment registration and blood product listing information, as well as the name, address, and phone number of its U.S. agent.

Among other uses, this information assists FDA in its inspections of facilities and is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply. Form FDA 2830 is used to collect this information.

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.

In the Federal Register of August 11, 2014 (79 FR 46838), 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	Form FDA 2830	No. of Respondents	No. 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	68	1	68	1	68
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40	Re-registration	2,615	1	2,615	0.5 (30 minutes)	1,308
607.21, 607.25, 607.30(a), 607.31, and 607.40	Product Updating List	166	1	166	0.25 (15 minutes)	42
Total						1,418

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

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

Dated: January 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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