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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2875]

Agency Information Collection Activities; Submission for OMB 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 the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by ***[insert date 30 days after date of publication in the Federal Register].***

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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, by December 31 of each year, his or her name, place of business and all such establishments, and 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) requires certain establishments that engage in the manufacture of blood products to register and to submit a list of blood products in commercial distribution. Section 607.21 requires the establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a blood product listing at that time. In addition, establishments are required to 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 registration and blood product listing. Section 607.25 indicates the information required for establishment registration and blood product listing. Section 607.26 requires for certain changes an amendment to the establishment registration to be made within 5 days of such changes. Section 607.30 requires establishments to update, as needed, their blood product listing information every June and at the annual registration. Section 607.31 requires that additional blood product listing information be provided upon FDA request.

Among other uses, this information assists FDA in its inspections of facilities, and its collection 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. The likely respondents are blood banks, blood collection facilities, and blood component manufacturing facilities.

FDA estimates the burden of this collection of information based upon the past experience of the Center for Biologics Evaluation and Research, Division of Blood Applications in regulatory blood establishment registration and product listing. Most blood banks are familiar with the regulations and registration requirements to fill out this form.

In the **Federal Register** of September 3, 1999 (64 FR 48408), the agency requested comments on the proposed collection of information. No significant comments were received.

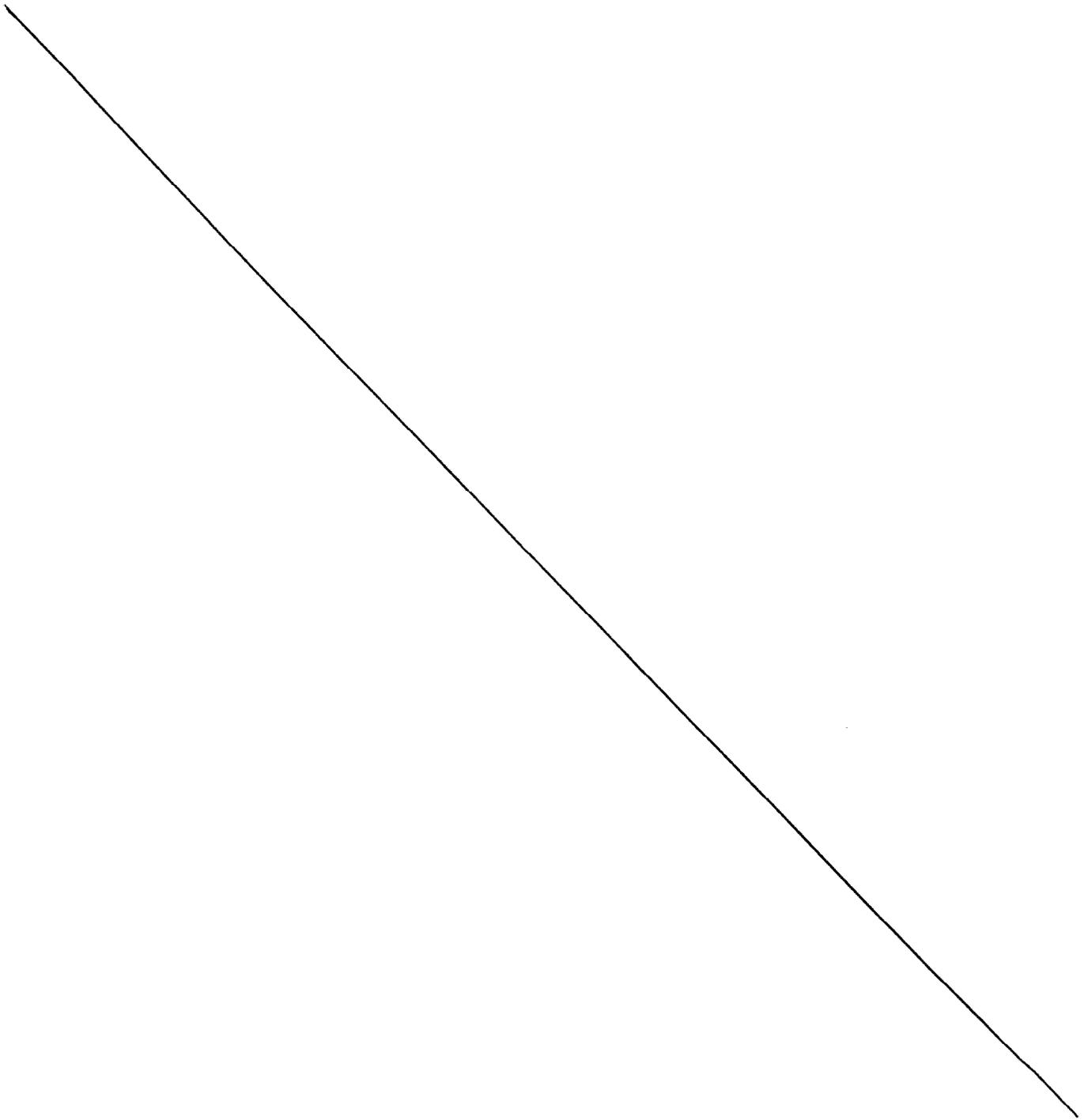


TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN'

21 CFR Sections	Form FDA 2830	No. of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
607.20(a), 607.21, 607.22, and 607.25	Initial Registration	300	1	300	1	300
607.21, 607.22, 607.25, 607.26, and 607.31	Re-registration	3,300	1	3,300	0.5	1,650
607.21, 607.25, 607.30, and 607.31	Product Listing Update	75	1	75	0.25	19
Total						1,969

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

Dated: December 10, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning, and Legislation



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