

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 02N-0319]

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.

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SUMMARY: The Food and Drug Administration (FDA) is announcing that the 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: 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: Stuart Shapiro, 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.

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, 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 and products. Section 607.20(a) requires certain establishments that engage in the manufacture of products to register and to submit a list of products in commercial distribution. Section 607.21 requires the establishments entering into the manufacturing of products to register within 5 days after beginning such operation and to submit a product listing at that time. In addition, establishments are required to register annually between November 15 and December 31 and update their product listing every June and December. Section 607.22 requires the use of Form FDA 2830 for registration and product listing. Section 607.25 indicates the information required for establishment registration and product listing. Section 607.26 requires certain changes to be submitted as an amendment to the establishment registration within 5 days of such changes. Section 607.30 requires establishments to update, as needed, their product listing information every June and at the annual registration. Section 607.31 requires that additional product listing information be provided upon FDA request. Section 607.40 requires foreign product establishments to

register and submit the product listing information, the name and address of the establishment, and the name of the individual responsible for submitting product listing information. 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 supply. Form FDA 2830, Establishment Registration and Product Listing, is used to collect this information. The likely respondents are banks, collection facilities, and component manufacturing facilities. FDA estimates the burden of this collection of information based upon the database and past experience of the Center for Biologics Evaluation and Research, Division of Applications in regulatory establishment registration and product listing. Most banks are familiar with the regulations and registration requirements to fill out this form.

In the **Federal Register** of August 2, 2002 (67 FR 50445), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received. The comment agrees that the information collection is necessary and the Form FDA 2830 is helpful with the registration process.

The comment stated that we underestimated the hours per response regarding the initial registration and product listing update. The comment stated that it might take up to 2 hours to complete the initial registration and 0.5 hours to complete the product listing update. We decline to change the estimates based on our review of the activities associated with completing the form. Although it may take some establishments longer to complete the form, others may complete the form more quickly. Since the reporting burden includes an estimated average of the time to complete the various activities

associated with the form, we believe that the current burden estimates accurately reflect the range of time to complete the form.

The comment also requested that the annual registration process be automated so that each facility could electronically submit the form, if they desire to do so, and also requested that we continue to send a hard copy of the form and instructions as a reminder to registrants to re-register. We are currently in the process of setting up a program for electronic registration. Use of the electronic system will be voluntary. We intend to continue sending a hard copy of the form and instructions for the foreseeable future.

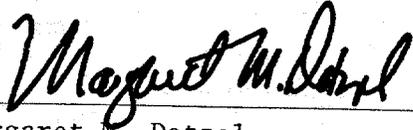
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR	Form FDA 2830	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
607.20(a), 607.21, 607.22, 607.25, and 607.40	Initial registration	300	1	300	1	300
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40	Re-registration	2,867	1	2,867	0.5	1,434
607.21, 607.25, 607.30, 607.31, and 607.40	Product listing update	75	1	75	0.25	19
Total						1,753

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

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Dated: 11/7/02
November 7, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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