team and the Minority Male (Min-Male) Consortium.

(5) Central State University will convene a meeting with the Advisory Board and the Family Life Center Directors three times a year.

(6) Central State University will monitor the activities of the funded institutions to ensure compliance with the intent of the program.

(7) Central State University will conduct a yearly evaluation of the activities of each of the funded institutions, as well as the overall project.

*OMH Responsibilities*

Substantial programmatic involvement is as follows:

(1) OMH will provide technical assistance and oversight as necessary for the overall design of the Family and Community Violence Prevention Program.

(2) OMH will develop the evaluation criterion for the selection and funding of applications.

(3) OMH will manage the review and selection of applications and ensure the absence of conflict of interest in the review process.

(4) OMH will have final approval of the Advisory Board membership.

(5) OMH will provide assistance to the Management Team on program strategies, direction, evaluation activities, and decisions related to adjustments in funding levels of participating institutions.

(6) OMH will participate in the planning of and attend all of the Advisory Board/Family Life Center Directors meetings.

(7) OMH will participate in site visits to the participating institutions as deemed appropriate by OMH staff.

**WHERE TO OBTAIN ADDITIONAL INFORMATION:** If you are interested in obtaining additional information regarding this project, contact Ms. Cynthia H. Amis, Director, Division of Program Operations, Office of Minority Health, 5515 Security Lane, Suite 1000, Rockville, Maryland 20852, telephone number (301) 594–0769.

The Catalog of Federal Domestic Assistance number is 93.910.

Clay E. Simpson, Jr.,

*Deputy Assistant Secretary for Minority Health.*

[FR Doc. 97–6325 Filed 3–12–97; 8:45 am]

**BILLING CODE 4160–17–M**

## Food and Drug Administration

**[Docket No. 96N–0402]**

## Agency Information Collection Activities; Submission for OMB Review; Comment Request

**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 April 14, 1997.

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

**FOR FURTHER INFORMATION CONTACT:** Linda L. Brna, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–3158.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the Paperwork Reduction Act of 1995 (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)

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the 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 21 CFR part 607, FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products. Under these regulations, the agency seeks the information required by the act, including the location of the facility, name of the reporting official, type of ownership, type of establishment, and identification of blood and blood products being manufactured. 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, Blood Establishment Registration and Product Listing, 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 as follows: 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 with new blood banks, the time needed for industry to complete the FDA 2830 is estimated to be 1 hour. For annual re-registration of blood banks, the time needed for industry to complete the FDA 2830 form is estimated to be one-half hour because re-registrants only need to refer to their files or written instructions for a small portion of the information required. Blood banks should be familiar with the regulations and registration requirements to fill out this form.

ESTIMATED ANNUAL REPORTING BURDEN

| Form No. FDA 2830 (21 CFR Part 607) | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Initial registration | 300 | 1 | 300 | 1 | 300 |
| Re-registration | 3,000 | 1 | 3,000 | 0.5 | 1,500 |
| Total | 3,300 | | 3,300 | | 1,800 |

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

Dated: March 5, 1997

William K. Hubbard,

*Associate Commissioner for Policy Coordination*

[FR Doc. 97–6356 Filed 3–12–97; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 96N–0192]**

## Agency Information Collection Activities; Submission for OMB Review; Comment Request

**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 April 14, 1997.

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

**FOR FURTHER INFORMATION CONTACT:** Linda L. Brna, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–3158.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use; Use of Form FDA 356h

FDA is the Federal agency charged with the responsibility for determining that drugs, including antibiotic drugs, and biologics are safe and effective. Manufacturers of a drug, biologic, or an antibiotic drug for human use must file applications for FDA approval of the product prior to introducing it into interstate commerce. Statutory authority for the collection of this information is provided by sections 505(a), (b), and (j) and 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a), (b), and (j) and 357) and section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). All manufacturers of new drugs and antibiotics for human use regulated under the act must submit an application for review and approval to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) prior to marketing a drug or antibiotic in interstate commerce (21 CFR 314.50). All manufacturers of generic drugs, including generic antibiotic drugs for human use, regulated under the act must submit an abbreviated new drug application (ANDA) to CDER or CBER or an abbreviated antibiotic drug application (AADA) to CDER for review and approval prior to marketing a generic drug in interstate commerce (21 CFR 314.94). Most manufacturers of biological products regulated under the PHS Act must submit an establishment license application and a product license application or a biologics license application for review and approval to CBER prior to marketing a biological product in interstate commerce (21 CFR 601.2). Blood and blood components fall within the category of biological products. All establishments collecting and/or preparing blood and blood components for sale or distribution in interstate commerce are subject to the licensing application provisions of section 351 of the PHS Act. Manufacturers of a drug, biologic, or an antibiotic drug for human use are required to file supplemental applications for all important changes to applications previously approved prior to implementing such changes (21 CFR 314.70, 314.71, 314.97, and 601.12).

Form FDA 356h has been revised for CDER-regulated products to include identification of different types of supplemental applications. It has also been modified to include a section for establishment information pertaining to CBER-regulated products and the CBER licensing process.

The information provided by manufacturers with the revised application form is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that drugs, biologics, and antibiotics for human use have been shown to be safe and effective. Form FDA 356h was developed initially as a checklist to assist manufacturers in filing a drug application and has been previously used only by manufacturers of products regulated under the act. The revised form has been harmonized for use by manufacturers of products regulated under the act or under the PHS Act and will be used by industry regulated by both CDER and CBER. The harmonized application form serves primarily as a checklist for firms to gather and submit to the agency studies and data that have been completed. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. The form will also provide key information to the agency for efficient handling and distribution to the appropriate staff for review. The revised form will replace a number of different application forms that are now used for these products and is intended to help harmonize the application process.

In the Federal Register of October 1, 1996 (61 FR 51285), the agency requested comments on the proposed collection of information using the harmonized application form. FDA received five responses to the docket, all of which were generally supportive of the harmonized application form. One comment expressed concern that the requirement to select a single supplement type on the form would result in an increased reporting burden. The comment indicated that selection of a single supplement type would require the filing of multiple supplements in order to respond to an agency information request letter containing several diverse issues. The comment may have misunderstood the distinction between a supplement to an approved application and an amendment to a pending application. A response to an agency information request letter is an amendment to a pending application, no matter how many individual subjects are addressed. This is clarified in the instruction sheet for the form.

There were also a number of editorial comments on the form itself. Some of these have resulted in minor modifications to the form. Other editorial comments and requests for clarification are addressed in the instructions for use of the form.

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