

limited set of early literacy, language, and numeracy skills. Social-emotional development of Head Start children reported by classroom teachers will be collected in HSNRS twice a year using a standardized rating scale developed for HSNRS. The social-emotional

development scales will be field-tested in spring 2006 prior to national implementation in fall 2006. Head Start teachers will rate children in their classrooms on the aspects of cooperative classroom behaviors, preschool learning behaviors, and problem behaviors.

HSNRS will also collect health and safety information on children and programs, including children's height and weight, immunization status, receipt of dental care, and occurrences of injuries requiring medical attention. Respondents: Head Start children and Head Start staff.

ANNUAL BURDEN ESTIMATES

| Respondents and activities   | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| <b>Fall Implementation</b>   |                       |                                    |                                   |                    |
| Head Start Children: Participate in Child Assessments .....  | 425,000               | 1                                  | 1/4                               | 106,250            |
| Head Start Staff (Assessors): Participate in Training-on-Child Assessments .....                     | 25,000                | 1                                  | 4                                 | 100,000            |
| Head Start Staff (Local NRS Trainers): Participate in Training-on-Child Assessments .....            | 1,800                 | 1                                  | 4                                 | 7,200              |
| Head Start Staff (Assessors): Administer Child Assessments .....                                     | 25,000                | 17                                 | 1/4                               | 106,250            |
| Head Start Teachers: Participate in Training on Social-Emotional Development Ratings .....           | 38,500                | 1                                  | 1                                 | 38,500             |
| Head Start Teachers: Complete Social-Emotional Development Ratings .....                             | 38,500                | 11                                 | 1/6                               | 70,583             |
| Head Start Teachers: Complete Child Health Questions .....   | 38,500                | 11                                 | 1/12                              | 35,292             |
| Head Start Staff: Complete Health and Safety of Program Questions .....                              | 1,800                 | 1                                  | 1/12                              | 150                |
| Head Start Staff: Enter Information on CBRS .....  | 1,800                 | 1                                  | 3                                 | 5,400              |
| <b>Spring Implementation</b>   |                       |                                    |                                   |                    |
| Head Start Children: Participate in Child Assessments .....  | 425,000               | 1                                  | 1/4                               | 106,250            |
| Head Start Staff (Assessors): Participate in Refresher Training-on-Child Assessments .....           | 25,000                | 1                                  | 4                                 | 100,000            |
| Head Start Staff (Local NRS Trainers): Participate in Training-on-Child Assessments .....            | 1,800                 | 1                                  | 4                                 | 7,200              |
| Head Start Staff (Assessors): Administer Child Assessments .....                                     | 25,000                | 17                                 | 1/4                               | 106,250            |
| Head Start Teachers: Participate in Refresher Training on Social-Emotional Development Ratings ..... | 38,500                | 1                                  | 1/4                               | 19,250             |
| Head Start Teachers: Complete Social-Emotional Development Ratings .....                             | 38,500                | 11                                 | 1/6                               | 70,583             |
| Head Start Teachers: Complete Child Health Questions .....   | 38,500                | 11                                 | 1/12                              | 35,292             |
| Head Start Staff: Complete Health and Safety of Program Questions .....                              | 1,800                 | 1                                  | 1/12                              | 150                |
| Head Start Staff: Enter Information on CBRS .....  | 1,800                 | 1                                  | 3/2                               | 2,700              |
| Total Annual Burden Estimates .....  |                       |                                    |                                   | 917,300            |

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection: E-mail: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 18, 2006.  
**Robert Sargis,**  
*Reports Clearance Officer.*  
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**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0327]

**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 February 24, 2006.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (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—(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 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 of each year. Section 607.22 requires the use of Form FDA 2830, Blood Establishment Registration and Product Listing, for initial registration, for annual registration, and for blood product listing. Section 607.25 indicates the information required for establishment registration and blood product listing. Section 607.26 requires certain changes to be submitted as amendments to the establishment registration within 5 days of such changes. Section 607.30 requires

establishments to update 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 requires foreign blood product establishments to register and submit the blood product listing information, the name and address of the establishment, and the name of the individual responsible for submitting 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 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.

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 24, 2005 (70 FR 49655), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section                                     | 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   | 100                | 1                             | 100                    | 1                  | 100         |
| 607.21, 607.22, 607.25, 607.26, 607.31, and 607.40 | Reregistration         | 2,775              | 1                             | 2,775                  | 0.5                | 1,388       |
| 607.21, 607.25, 607.30, 607.31, and 607.40         | Product listing update | 180                | 1                             | 180                    | 0.25               | 45          |
| Total  |                        |                    |                               |                        |                    | 1,533       |

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

Dated: January 13, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0190]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export Certificates for FDA Regulated Products

**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 February 24, 2006.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:**

Jonna Capezzuto, Office of Management Programs (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.

#### Export of FDA Regulated Products—Export Certificates—(OMB Control Number 0910-0498)—Extension

In April 1996, a law entitled “The FDA Export Reform and Enhancement Act of 1996” amended sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the act provides that persons exporting certain FDA-regulated products may request that FDA certify that the products meet the requirements of sections 801(e) or 802 or other requirements of the act. This section of the law requires that FDA issue certification within 20 days of receipt of the request and charge firms up to \$175 for the certifications.

This section of the act authorizes FDA to issue export certificates for regulated

pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for pharmaceuticals, biologics, and devices that are not legally marketed, but are acceptable to the importing country as specified in sections 801(e) and 802 of the act. Section 801(e)(4) of the act provides that FDA shall, upon request, issue certificates for human drugs and biologics, animal drugs, and devices that either meet the applicable requirements of the act and may be legally marketed in the United States or may be legally exported under the act although they may not be legally marketed in the United States. The act does not require FDA to issue certificates for food, including animal feeds, food and feed additives, and dietary supplements, or cosmetics. However, because foreign governments may require certificates for these types of products, the agency intends to continue to provide this service as resources permit. FDA issues six types of certificates: (1) Certificate to Foreign Government (FDA 3613), (2) Certificate of Exportability (FDA 3613a), (3) Certificate of a Pharmaceutical Product (FDA 3613b), (4) Non-clinical Research Use Only Certificate (FDA 3613c), Office of Cosmetics and Colors “Certificate” (Exports) Application (FDA 3613d), and Food Export Certificate Application (FDA 3613e). Table 1 of this document lists the different certificates and details their uses:

TABLE 1. LIST OF FDA EXPORT CERTIFICATES

| Certificate Name   | Form FDA | Use   | Issuing FDA Center  |
|--|----------|---|---|
| Certificate to Foreign Government                                  | 3613     | For the export of products that can be legally marketed in the United States.   | Center for Biologic Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM) |
| Certificate of Exportability                                       | 3613a    | For the export of products that cannot be legally marketed in the United States but meet the requirements of sections 801(e) or 802 of the act and may be legally exported.                           | CBER; CDRH; CVM   |
| Certificate of a Pharmaceutical Product                            | 3613b    | For use by the importing country when considering whether to license the product in question for sale in that country. Conforms to the format established by the World Health Organization.           | CBER; Center for Drug Evaluation and Research; CVM  |
| Non-Clinical Research Use Only Certificate                         | 3613c    | For the export of non-clinical research use only product, material, component that is not intended for human use which may be marketed in, and legally exported from the United States under the act. | CBER; CDRH  |
| Office of Cosmetics and Colors “Certificate” (Exports) Application | 3613d    | For the export of products that are identified by the requester as cosmetics.   | Center for Food Safety and Applied Nutrition (CFSAN)  |