

impact minority and disadvantaged citizens in America; and

7. The MHPF member institutions were founded specifically to improve the health status of medically underserved African Americans and other ethnic minority groups, and play a critical role in building the nation's health care workforce.

### C. Availability of Funds

Approximately \$200,000 is available in FY 2000 to fund this cooperative agreement. Sub-awards will be funded through CDC and ATSDR. A cumulative award of approximately \$2,000,000 to the MHPF is expected during FY 2000. Subawards will range from \$25,000 to \$450,000. It is expected that the awards will begin on September 30, 2000. Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Applications that exceed the funding cap of \$450,000 will be excluded from the competition and returned to the applicant.

### D. Where To Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Sheri Disler, Senior Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, MS E-15, Koger Center, Colgate Building, Atlanta, Georgia 30341-3724. Telephone 770-488-2756. E-mail address [sjd9@cdc.gov](mailto:sjd9@cdc.gov).

Program technical assistance may be obtained from Karen E. Harris, Senior Advisor for Research Projects, Office of the Associate Director for Minority Health, Office of the Director, Centers for Disease Control and Prevention, 1600 Clifton Road, Northeast, Mailstop D-39, Atlanta, Georgia 30333. Telephone (404) 639-4313, E-mail address [keh2@cdc.gov](mailto:keh2@cdc.gov).

Dated: June 23, 2000.

**John L. Williams,**

*Director, Procurement and Grants Office,  
Centers for Disease Control and Prevention  
(CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-0914]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Importer's Entry Notice

**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 July 31, 2000.

**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. Capezutto, 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.

#### Importer's Entry Notice (OMB Control Number 0910-0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Ensuring that

foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products; and (2) preventing shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of the goods to their final destination; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at the same time he/she files an entry for import with the U.S. Customs Service. FDA uses the information to make admissibility decisions about FDA-regulated products offered for import into the United States.

The annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995. The total number of entries submitted to the automated system in FY 1999 was 5,077,493. The total number of entries less the disclaimer entries will represent the total FDA products entered into the automated system. A total of 51 percent of all entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA contacting some potential respondents. Disclaimer entries are not FDA commodities.

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

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

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,886	652	2,533,355	.14	354,669

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

In the **Federal Register** of March 22, 2000 (65 FR 15340), the agency requested comments on the proposed collections of information. No comments were received.

Dated: June 22, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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**BILLING CODE 4160-01-F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-0836]

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

**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 July 31, 2000.

**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:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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.

#### Environmental Impact Considerations—Part 25 (21 CFR Part 25)—(OMB Control Number 0910-0322)—Extension

FDA is requesting OMB approval for the reporting requirements contained in FDA's regulation "Environmental Impact Considerations" (part 25).

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4347) states national environmental objectives and imposes upon each Federal agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

FDA's NEPA regulations are at part 25. All applications or petitions requesting agency action require the submission of an Environmental Assessment (EA) or a claim of categorical exclusion. Section 25.15(a) and (d) specify the procedures for submitting to FDA a claim for a categorical exclusion (certain classes of FDA-regulated actions have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS). Section 25.40(a) and (c) specify the content requirements for EA's for nonexcluded actions.

This collection of information is used by FDA to assess the environmental impact of agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications

(when not eligible for categorical exclusion) for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse effects cannot be avoided, the agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** notice also filed for comment at the Environmental Protection Agency. The final EIS including the comments received is reviewed by the agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact. When the agency finds that no significant environmental effects are expected, the agency prepares a finding of no significant impact (FONSI).

#### I. Estimated Annual Reporting Burden for Human Drugs

Under 21 CFR 312.23(a)(7)(iv)(e), 21 CFR 314.50(d)(1)(iii), and 21 CFR 314.94(a)(9)(i), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 1998, FDA received 2,427 IND's from 1,874 sponsors, 129 NDA's from 80 applicants, 2,500 supplements to NDA's from 238 applicants, 345 ANDA's from 101 applicants, and 3,713 supplements to ANDA's from 165 applicants. FDA estimates that it receives approximately 9,094 claims for categorical exclusions as required under § 25.15(a) and (d), and 20 EA's as required under § 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA.