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: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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 goods to their final destinations; (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 he same time he/she files an entry for import with the U.S. Custom Service. FDA uses this 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 2002 was 5,496,954. The total number of entries less the disclaimer entries will represent the total FDA products entered into the automated system. A total of 53 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.

In the **Federal Register** of May 23, 2003 (68 FR 28235), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 801 for FY 2002 Updated	3,406	652	2,955,595	.14	413,833

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

Dated: August 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21982 Filed 8–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0191]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Submission of Validation Data for Reprocessed Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Submission of Validation Data for Reprocessed Single-Use Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 8, 2003 (68 FR 40676), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0514. The approval expires on January 31, 2004.

A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: August 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21983 Filed 8–27–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0364]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Annual Reports for New Drug Applications and Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—