FDA's estimates are based on actual data collected from industry over the past 3 years, where there has been an average of 1,600 annual responses to FDA from 145 respondents each year.

3. Export of Medical Devices—Foreign Letters of Approval—21 U.S.C. 381(e)(2) (OMB Control No. 0910–0264—Reinstatement)

Section 801(e)(2) of the act (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device.

The written authorization from the foreign country is used by the Office of Compliance, CDRH in determining if the foreign country has any objection to the importation of the device into their country. In FY 95, the Office of Compliance received approximately 800 requests from U.S. firms to export medical devices under section 801(e)(2) of the act. If approval letters from foreign governments were not submitted by the requesting firm, CDRH would then have had to contact various embassies (via telephone, for example) to seek their approval, which would have been time consuming and costly.

The respondents to this collection of information are companies that seek to export medical devices.

The foreign letters of approval are submitted under a statutory information collection requirement only. Because there is no additional burden attributable to a regulation, no burden chart is included.

4. Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(a)(2) and (e) (OMB Control No. 0910–0131—Reinstatement)

Under sections 501(c) and 502(a) of the act (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(a)(2) and (e) (21 CFR 801.150(a)(2) and (e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(a)(2) and (e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices are nonsterile, being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices. To discontinue this reporting and recordkeeping procedure would place an economic hardship on the industry and an additional burden on FDA to monitor product in interstate commerce for failure to comply with adulteration and misbranding provisions of the act.

The respondents to this collection of information are device manufacturers and contract sterilizers.

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

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150	90	20	1,800	4	7,200

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

No burden has been estimated for the recordkeeping requirement in § 801.150(a)(2) because these records are maintained as a usual and customary part of normal business activities. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

FDA's estimate of the burden is based on actual data obtained from industry during the past 3 years where there are approximately 90 firms subject to this requirement.

Dated: February 25, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–5646 Filed 3–6–97; 8:45 am]

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Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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.

Proposed Project

Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—Extension, No Change—Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), Limitation on Prices of Drugs Purchased by Covered Entities. Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

Because of the potential for disputes and/or audits involving covered entities and participating drug manufacturers; the HRSA Office of Drug Pricing Program has developed an informal dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

Audit guidelines: A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer must submit a request for an audit of a covered entity to the HRSA Office of Drug Pricing Program. The manufacturer must then submit an audit work plan describing the audit to the HRSA Office of Drug Pricing Program for review. The manufacturer will submit copies of the audit report to the HRSA Office of Drug Pricing Program for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General.

Dispute resolution guidelines: Because of the potential for audit and other disputes involving covered entities and participating drug manufacturers, the HRSA Office of Drug Pricing Program has developed an informal dispute resolution process, which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a dispute with the HRSA Office of Drug Pricing Program, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA Office of Drug Pricing Program. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

To date, there have been no requests for audits, and no disputes have reached the level where a committee review was needed. As a result, the estimates of annualized hour burden for audits and disputes have been reduced to the level shown in the table below.

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/response	Total burden hours
Audits:					
Audit request [1]	2	1	2	4	8
Audit workplan [1]	1	1	1	8	8
Audit report [1]	1	1	1	1	1
Entity response	1	1	1	16	16
Dispute resolution:					
Mediation request	5	1	5	8	40
Rebuttal	2	1	2	16	32
Total	10	1.2	12	8.75	105

[1] Prepared by the manufacturer.

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total burden
Dispute records	8	.5	4

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 26, 1997.

J. Henry Montes,

Director, Office of Policy and Information Coordination.

[FR Doc. 97–5560 Filed 3–6–97; 8:45 am]

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Customer Survey of Entities Eligible To Participate in the Drug Pricing Program—New

Section 602 of the Veterans Health Care Act of 1992 enacted Section 340B of the Public Health Service (PHS) Act, ''Limitation of Prices of Drugs Purchased by Covered Entities.'' This section provides that a manufacturer that sells outpatient drugs to covered