testing to manufacturers of in vitro diagnostic products and to organizations that use the tests for reasons other than providing diagnostic information to physicians and patients. FDA has established certain labeling requirements for suppliers of ASR's and some requirements regarding advertising and promotional materials for ASR's. FDA believes the labeling requirements and restrictions on advertising and promotion are necessary to ensure that laboratories developing tests from ASR's have sufficient information to use the ASR's appropriately and to limit specific claims by manufacturers, because these ASR's are intended to be used as ingredients in a variety of ways by laboratories qualified to do high complexity testing.

The most likely respondents to this information collection will primarily be medical device manufacturers of in vitro products, clinical laboratories, and third parties.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
809.10(e)	300	25	7,500	1	7,500
809.30(d)	300	25	7,500	1	7,500
Totals					15,000

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

The burden is based on the estimate and averaging of five establishments. The number of establishments manufacturing or supplying ASR's ranged from 100 to 500 with the average being 300. Consequently, FDA estimates the number of ASR manufacturers and suppliers subject to the reporting requirements is approximately 300.

The number of ASR's being manufactured was derived by asking the same five establishments. Three of the establishments gave estimates for the number of ASR's that ranged from 5,000 to 10,000, with the average being 7,500.

In order to determine the number of ASR's manufactured by each respondent, FDA used the average number of ASR's manufactured and divided it by the number of ASR manufacturers (7,500 ÷ 300). Consequently, the estimate of the number of ASR's manufactured by each respondent is approximately 25.

FDA estimates for each ASR, it adds approximately 1 additional hour to the design and review process for new labels to conform with the requirements of § 809.10(e) (21 CFR 890.10(e)). FDA also estimates that the total reporting hour burden is approximately 7,500 hours (300 x 25).

FDA estimates for each ASR it adds approximately 1 hour to the preparation and review time for the professional materials to ascertain compliance with § 809.30(d). FDA estimates that the total reporting hour burden for promotional materials is approximately 7,500 (300 X 25).

Dated: September 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–23546 Filed 9–13–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1303]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Agreement for Shipment of Devices for Sterilization

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 October 16, 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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control No. 0910–0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (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(e) (21 CFR 801.150(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(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. The respondents to this collection of information are device manufacturers and contract sterilizers.

In the **Federal Register** of June 12, 2000 (65 FR 36816), the agency requested comments on the proposed collection of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.150(e)	80	20	1,800	4	7,200
Total					7,200

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

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.

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.

Dated: September 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–23547 Filed 9–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–901–1 and HCFA–1763]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: Qualification Application and Supporting Regulations in 42 CFR Section 417.408 and 417.143;

Form No.: HCFA–901–1 (OMB# 0938–0470);

Use: Prepaid health plans must meet certain regulatory requirements to be federally qualified health maintenance organizations. This application is the collection form used to obtain the information from health plans that allow HCFA staff to determine compliance with the regulations;

Frequency: Other: One-time;

Affected Public: Business or other for-profit, not-for-profit institutions, and State, Local, or Tribal Government;

Number of Respondents: 35;

Total Annual Responses: 35;

Total Annual Hours: 3,500.

(2) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Request for Termination of Premium Hospital and/or Supplementary Medical Insurance and Supporting Regulations in 42 CFR 406.28 and 407.27;

Form No.: HCFA–1763 (OMB No. 0938–0025);

Use: The HCFA–1763 is used by beneficiaries to request voluntary termination from premium hospital and/or supplementary medical insurance;

Frequency: One time only;

Affected Public: Individuals or Households, Federal Government, and State, Local or Tribal Government;

Number of Respondents: 14,000;

Total Annual Responses: 14,000;

Total Annual Hours: 5,833.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 28, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–23625 Filed 9–13–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Development of a Molecular Rotation Engine

An opportunity for a Cooperative Research and Development Agreement (CRADA) is available for collaboration with the NCI Intramural Division of Basic Sciences for the development of an ATP-driven, molecular-based rotation engine. The opportunity is open to a multi or single party collaboration that would require the input of molecular biology and genetic engineering experience on the part of the potential collaborator or collaborators.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of Opportunity for Cooperative Research and Development Agreement.