FALL 2001—Continued

Instruments	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
Center Directors	24	1	1	24
Classroom Teachers	48	1	1	48
Totals for Fall 2001	744			642

SPRING 2002

Instruments	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
Head Start child Assessments	520	1	2/3	343
Head Start Teacher ratings	48	11	1/4	132
Classroom Teachers	48	1	1	48
Totals for Spring 2002	616			523

FALL 2002

Instruments	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
Head Start Child Assessments	920	1	2/3	607
Head Start Teacher Ratings	80	12	1/4	240
Center Directors	24	1	1	24
Education Coordinators	24	1	.75	18
Classroom Teachers	80	1	1	80
Totals for Fall 2002	1,128			969

SPRING 2003

Instruments	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
Head Start Child Assessments	800	1	2/3	528
Head Start Teacher Ratings	80	10	1/4	200
Classroom Teachers	80	1	1	80
Totals for Spring 2003	960			808

Total 2001: 642.
Total 2002: 1492.
Total 2003: 808.
Estimated Annual Burden Hours: 981.

Note: Estimated Annual Burden Hours are based on an average of 2001, 2002, and 2003 estimated burden hours.

FOR FURTHER INFORMATION CONTACT: Copies of the proposed collection may be obtained 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.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503; Attn: Desk Officer for ACF.

Dated: August 22, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–21543 Filed 8–24–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0222]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Third-Party Review Under FDAMA

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 September 26, 2001.

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.

Medical Devices; Third-Party Review Under FDAMA (OMB Control No. 0910–0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) established a new section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. As with the third-party pilot program conducted previously by FDA, participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviews should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time. This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low to moderate risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

In the **Federal Register** of May 29, 2001 (66 FR 29142), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for accreditation	40	1	40	24	960
510k reviews conducted by accredited third parties	35	4	140	40	5,600
Total					6,560

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510(k) reviews	35	4	1,140	10	1,400

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

The burdens are explained as follows:

1. Reporting

a. *Requests for accreditation.* Under the agency's third-party review pilot program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. Under this expanded program, the agency anticipates that it will not see a significant increase in the number of applicants. Therefore, the agency is estimating that it will receive 40 applications. The agency anticipates that it will accredit 35 of the applicants to conduct third-party reviews.

b. *510(k) reviews conducted by accredited third parties.* In the 18 months under the third-party review pilot program, FDA received only 22 510(k)s that requested and were eligible for review by third parties. Because the third-party review program is not as limited in time, and is expanded in scope, the agency anticipates that the number of 510(k)s submitted for third-party review will remain the same as they were during the last OMB approval in 1998. The agency anticipates that it will receive approximately 140 third-party review submissions annually, i.e., approximately 4 annual reviews per each of the estimated 35 accredited reviewers.

2. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 140 annual submissions of 510(k)s for third-party review.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) is derived from agency records and experience.

Dated: August 20, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21529 Filed 8–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.