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	140	60	8,400

[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 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 new 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 increase. 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.

Prior to the implementation of the program, FDA will publish in the **Federal Register** a notice of OMB's decision to approve, modify, or disapprove the information collection provisions. 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.

Dated: May 19, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–13799 Filed 5–20–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0438]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''User Fee Cover Sheet'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 13, 1998 (63 FR 7420), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0297. The approval expires on April 30, 2001.

Dated: May 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13648 Filed 5–21–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0327]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Petition for Administrative Stay of Action'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 12, 1998 (63 FR 7173 and 7174), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0194. The approval expires on April 30, 2001.

Dated: May 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13649 Filed 5–21–98; 8:45 am]

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