ESTIMATED ANNUAL REPORTING BURDEN

Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3038	33	70	2,310	.10	231

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

This estimate is based on the number of certificates received in 1996.

Dated: July 31, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20868 Filed 8–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0143]

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 ''Citizen Petition'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 28, 1997 (62 FR 22959), 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). OMB has now approved the information collection and has assigned OMB control number 0910–0183. The approval expires on June 30, 2000. 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: July 31, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–20869 Filed 8–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0323]

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

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 (the PRA).

DATES: Submit written comments on the collection of information by September 8, 1997.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Notice of Participation—(21 CFR 12.45) (OMB Control Number 0910–0191—Reinstatement)

Under part 12 (21 CFR part 12) regulations issued under sections 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393), any interested person may participate in a formal evidentiary hearing, either personally or through a representative by filing a notice of participation under § 12.45. Section 12.45 requires that any person filing a notice of participation state the person's specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present documentary evidence on testimony at the hearing and will comply with specific requirements in § 12.85 or, in the case of a hearing before a Public Board of Inquiry, in 21 CFR 13.25, concerning disclosure of data and information by participants. A participant's appearance can be struck by the presiding officer in accordance with § 12.45(e).

The information obtained is used by the presiding officer and other participants in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation.

The affected respondents are individuals or households, State or local governments, not-for-profit institutions and businesses or other for-profit groups and institutions.

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

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	92	1	92	3	276

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