Petition For Administrative Stay of Action—21 CFR Part 10.35 (OMB Control Number 0910—0194)—Reinstatement

Section 10.35 (21 CFR 10.35), issued under the authority of section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may file a petition for an administrative stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action. Such a petition must: (1) Identify the decision involved; (2) state the action requested—including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. The information provided in the petition is used by the agency to determine whether the requested stay should be granted.

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
10.35	7	1	7	100	700

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

The burden estimate for this collection of information is based on FDA's experience with petitions for administrative stay of action over the past 3 years. Agency personnel responsible for processing the filing of petitions for administrative stays of action estimate that seven such petitions are received by the agency annually, with each requiring approximately 100 hours of preparation time.

Dated: November 19, 1997

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–30982 Filed 11–25–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N–0396]

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 December 26, 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: Margaret R. 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 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.

Reports of Corrections and Removals for Manufacturers, Importers, and Distributors of Medical Devices (21 CFR 806.10 and 806.20).

In a final rule published in the **Federal Register** of May 19, 1997 (62 FR 27183), FDA issued regulations requiring that manufacturers, importers, and distributors of medical devices report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act (the act) that could present a risk to health. The collection of this information is required by section 519(f) of the act (21 U.S.C. 360i(f)). These regulations will help FDA to protect the public health by ensuring that the agency has current and complete information regarding those actions taken to reduce risks to health caused by devices. Reports of such actions will improve the agency's ability to evaluate device-related problems and to take prompt action against potentially dangerous devices.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20	440	1	440	10	4,400

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

In the final rule (62 FR 27183), the agency requested comments on the information collection provision of the new regulation. The 60-day comment period closed July 18, 1997. The agency received four comments. Comments received in response to the information collection provisions stated that: (1) The U.S. designated agent provisions should be reinstated; (2) the definition of risk to health is confusing and contradictory, and it raises the threshold of reports of corrective and removal actions to that of a voluntary recall, and as such will de facto result in the automatic classification of these reports as recalls; (3) FDA has underestimated the reporting burden; and (4) the recordkeeping requirements place undue burden on industry.

FDA disagrees with these comments. As discussed in the May 1997 final rule requiring reports of corrections and removals, FDA published a final rule staying the U.S. designated agent provisions of the medical device reporting (MDR) rule in the **Federal Register** of July 23, 1996 (61 FR 38346). FDA stayed those provisions in response to serious concerns on the part of regulated industry that the agency had not adequately considered the costs to and administrative burden on foreign firms. The same concerns apply to the U.S. designated agent provision included in the proposed rule to require reports of corrections and removals (59 FR 13828, March 23, 1994). FDA omitted that provision in the final rule (62 FR 27183) to allow the agency to continue to consider industry's concerns. The agency has not announced its decision on whether it will reinstate U.S. designated agent provisions in MDR or the corrections and removals rule, but intends to do so in the future.

FDA does not believe that the definition of ''risk to health'' in the corrections and removals rule is confusing or contradictory. The agency and manufacturers have used this same definition successfully under part 7 (21 CFR part 7), the voluntary recall rule, for over 20 years. Moreover, by using the definition of ''risk to health'' that appears in the voluntary recall rule, the agency believes that it has established an appropriate threshold for requiring reports of removals and corrections. The definition the agency adopted in the final rule is narrower than the one that appeared in the proposed rule and eliminates the burden on manufacturers of having to report corrections of minor or very remote health risks. Adoption of this definition does not affect recall procedures under part 7, which remain voluntary.

The agency does not believe that the reporting burden for reports of corrections and removals has been underestimated. The agency revised the reporting and recordkeeping burden estimate in the final rule upward based on a review of voluntary reporting data and industry complaint files. The comments did not submit any specific data as to what they believe to be the true costs of the rule.

The agency disagrees with the comment that recordkeeping requirements place an undue burden on industry. The statute requires manufacturers to keep records of corrections and removals that do not meet the requirements for reporting. The regulation implements this statutory requirement. FDA believes that the recordkeeping requirement of the corrections and removals rule carries out the statutory mandate and is appropriately tailored to the agency's mission of protecting the public health. The statute and the regulation require reporting only of events, corrections, and removals that are initiated to address a public-health risk. FDA believes that it has limited reporting requirements to information necessary to carry out its mission of protecting the public health.

Dated: November 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–31063 Filed 11–25–97; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4263–N–59]

Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: December 26, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: November 20, 1997.

David S. Cristy,

Director, Information Resources, Management Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Application for Homeownership Assistance Under Section 235 of the National Housing Act.

Office: Housing.

OMB Approval Number: 2502–0190.

Description of the Need for the Information and its Proposed Use: The information collection will be used to determine a homeowner's eligibility for and amount of financial assistance to be provided under Section 235, Homeowners Assistance Payments Program.

Form Number: HUD–93100.