

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]

BILLING CODE 4160-01-F

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.

Respondents: Individuals or Households and Business or Other For-Profit.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
HUD-93100	21,000		1		25		250

Total Estimated Burden Hours: 5,250.

Status: Reinstatement, with changes.

Contact: Diane Lobasso, HUD, (202) 708-2700 x2191; Joseph F. Lackey, Jr., OMB, (202) 395-7316.

Dated: November 20, 1997.

[FR Doc. 97-31071 Filed 11-25-97; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4263-N-60]

Submission of 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, Southwest, 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.

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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: Description of materials.

Office: Housing.

OMB Approval Number: 2502-0192.

Description of the Need for the Information and Its Proposed Use: Form HUD-92005 is needed so that builders and sponsors can describe the materials for the construction and other improvements to the single family property. This form and the drawings define the scope and limits of the proposed construction. This information is also used by HUD to estimate the value for FHA mortgage insurance to determine if the construction meets regulatory requirements.

Form Number: HUD-92005.

Respondents: Business or Other For-Profit and the Federal Government.

Frequency of Submission: On occasion.

Reporting Burden:

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
HUD-92005	2,500		20		.5		25,000