(revised Form FDA 356h) for vaccines or related products. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time, however, comments should be submitted by August 18, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product.'' This draft guidance document, when finalized, is intended to provide guidance to applicants in completing the CMC section and the establishment description information of revised Form FDA 356h. As announced in the **Federal Register** of July 8, 1997 (62 FR 36558), this form will be used as a single harmonized application form for all drug and licensed biological products. Use of the new harmonized Form FDA 356h, when fully implemented, will allow a biologic product manufacturer to submit one biologics license application instead of two separate applications (product license application and establishment license application).

This draft guidance document represents FDA's current thinking on the content and format of the CMC and Establishment Description sections of a license application for a vaccine or related product. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this draft guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The draft guidance document is intended to provide information and does not set forth requirements.

II. Request for Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by August 18, 1998, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: June 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–16291 Filed 6–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4349–N–24]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for 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:* July 20, 1998.

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: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–1305. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

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: June 12, 1998.

David S. Cristy,

Director, IRM Policy and Management Division.

Title of Proposal: Manufactured Home Construction and Safety Standards.

Office: Housing.

OMB Approval Number: 2502–0253.

Description of the Need for the Information and Its Proposed Use: The National Manufactured Housing Construction and Safety Standards Act authorized HUD to establish construction and safety standards for manufactured (mobile) homes and to enforce these standards. The standards require pertinent information in the form of labels and notices to be placed in each manufactured home. HUD needs this information to make sure manufacturers are complying with the standards.

Form number: None.

Respondents: State, Local or Tribal Governments, and businesses or other for-profit.

Frequency of submission: Monthly and recordkeeping.

Reporting burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
SAA Reports	432		1		.64		276
IPIA Reports	1,056		1		.60		633
Manufacturer Records	360,000		1		.16		57,600
Consumer Information Cards	360,000		1		.48		172,800
State Plans	12		40		1.00		480
Consumer Manuals	360,000		1		.08		28,800
Labels and Notices	360,000		1		.22		79,200

Total Estimated Burden Hours: 339,789.

Status: Reinstatement with changes.

Contacts: Stuart Margulies, HUD, (202) 708–6409; Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: June 12, 1998.

[FR Doc. 98–16329 Filed 6–18–98; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4349–N–25]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for 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:* July 20, 1998.

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: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–1305. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

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: June 12, 1998.

David S. Cristy,

Director, IRM Policy and Management Division.

Title of Proposal: Lead-Based Paint Hazard Control Grant Program Data Collection for Rounds Two and Three Grantees.

Office: Lead Hazard Control.

OMB Approval Number: 2539–0008.

Description of the Need for the Information and its Proposed Use: This data collection is designed to provide timely information to HUN regarding the implementation progress of the grantees on carrying out the Lead-Based Paint Hazard Control Grant Program. The information collection will also be used to provide Congress with status reports as required by Title X of the Housing and Community Development Act of 1992.

Form Number: 96005.

Respondents: State, Local, or Tribal Government.

Frequency of Submission: Quarterly.

Reporting Burden: