

3. SMDA to FDAMA: Guidance on FDAs Transition Plan for Existing Postmarket Surveillance Protocols (Docket No. 98D-0108 (FOD # 318)).

These guidance documents represent the agency's current thinking on postmarket surveillance. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

II. Electronic Access

In order to receive these guidance documents via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number found next to the title of the document listed above followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH Home Page includes information on the FDA Modernization Act, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Information on the FDA Modernization Act is available at <http://www.fda.gov/cdrh/modern/modact>.

A text-only version of the CDRH Web site is also available from a computer or VT-100 compatible terminal by dialing 800-222-0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for

general information, or arrow down for specific topics.

III. Comments

Interested persons may, by or before May 26, 1998, submit to the Dockets Management Branch written comments regarding these guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments will be considered in determining whether to revise or revoke the guidance documents.

Dated: February 19, 1998.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4263-N-86]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be 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: April 27, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing and Urban Development, 451-7th Street, SW, Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Marion Connell, telephone number (202) 708-6409 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information: to (1) Evaluate whether the proposed

collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Technical Suitability of Products Program Section 521 of National Housing Act.

OMB Control Number: 2502-0313.

Description of the need for the information and proposed use: HUD will use this engineering data to make a determination of technical suitability. Organizational and production data are used to establish company authority and whether the facilities and capability to produce the material or product are adequate. This prevents design organizations from using the government as a review board.

Form numbers: None.

Members of affected public: Manufacturer seeking acceptance of their product by HUD.

An estimation of the total numbers of hours needed to prepare the information collection is less than 1 hour and a more complex application could take up to 80 hours. The number of respondents is 50, frequency of response is one-time a year.

Status of the proposed information collection: reinstatement.

Authority: Section 236 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: February 19, 1998.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 98-4719 Filed 2-24-98; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4263-N-87]

Notice of Proposed Information Collection; Comment Request

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.