CDRH Staff'' (Docket Number 98D–0082) (FOD # 199), and

(6) ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (Docket No. 98D–0083) (FOD # 159).

These guidance documents represent the agency's current thinking on CDRH's implementation of the FDAMA. These guidance documents 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. Under FDA's ''Good Guidance Practices'' policy (62 FR 8961, February 27, 1997), each of these guidance documents is a Level 1 guidance document that may be implemented immediately because it is the subject of a new statute. FDA will review the comments received in order to determine whether to revise or revoke the guidance.

These guidance documents may contain collections of information that require OMB clearance under the Paperwork Reduction Act of 1995. FDA will seek such approval and provide an opportunity to comment, as appropriate.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the World Wide Web 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 these guidance documents, 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/modact/modern.html.

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.

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 followed by the pound sign (#). The appropriate FOD number is listed next to the title of the document in the list above. Then follow the remaining voice prompts to complete your request.

III. Comments

Interested persons may, by or before May 26, 1998 submit to the Dockets Management Branch (address above) written comments regarding these guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number for each guidance listed next to the title of the document in the list found previously. If you wish to comment on more than one guidance document, please submit a separate comment for each guidance document for which you wish to submit a comment. The guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

After May 26, 1998, written comments may be submitted at any time to Ron Jans (address above).

Dated: February 12, 1998

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–4841 Filed 2–20–98; 4:00 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98D–0106, 98D–0107, 98D–0108]

Medical Devices; Postmarket Surveillance; Guidance Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three guidance documents on postmarket surveillance of medical devices. These guidance documents are being issued in order to facilitate the implementation of the postmarket surveillance provisions of the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997. FDA will issue further guidance in the near future.

DATES: Submit written comments concerning these guidance documents by May 26, 1998.

ADDRESSES: Submit written to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of these guidance documents on a 3.5'' diskette to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to these guidance documents.

FOR FURTHER INFORMATION CONTACT: Anita Rayner, Center for Devices and Radiological Health (HFZ–543), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–0639.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 amended the act, among other things, to add section 522 (21 U.S.C. 360(l)) to require postmarket surveillance for certain medical devices. Section 522 was further amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115). As amended, section 522 of the act revises the criteria for determining which devices are subject to postmarket surveillance and revises the procedures for implementing postmarket surveillance. The revised provisions of section 522 become effective on February 19, 1998.

FDA is making the following guidance documents available at this time in order to facilitate the initial implementation of the revised postmarket surveillance provisions:

1. Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies (Docket No. 98D–0106 (FOD # 316));

2. Guidance on Procedures for Review of Postmarket Surveillance Submissions (Docket No. 98D–0107 (FOD # 317)); and

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.

[FR Doc. 98–4844 Filed 2–20–98; 3:59 pm]

BILLING CODE 4160–01–F

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]

BILLING CODE 4210–27–M

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.