PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: August 13, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–22154 Filed 8–13–98; 11:37 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 94P–0110 and 95N–0245]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Labeling: Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 the **Federal Register** of June 5, 1998 (63 FR 30615), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0351. The approval expires on July 31, 2001.

Dated: August 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–21997 Filed 8–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0565]

Off-the-Shelf Software Use in Medical Devices; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Off-the-Shelf Software Use in Medical Devices.'' This draft guidance document is not final or in effect at this time. The purpose of the draft guidance document is to describe the information that should be provided in a medical device application involving Off-the-Shelf (OTS) software. While the draft guidance document is not intended for compliance with Quality System requirements, many of the principles outlined may be helpful to device manufacturers in establishing design controls and validation plans for use of off-the-shelf software in their devices.

DATES: Submit written comments by November 16, 1998. After the close of the comment period, written comments may be submitted at any time to Daniel A. Spyker (address below).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ''Off-the-Shelf Software Use in Medical Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, 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 the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Daniel A. Spyker, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document was developed to address the many questions asked by medical device manufacturers regarding what they need to provide to FDA when they use OTS software. The response to these questions depends on the medical device in question and the impact on patient safety when the OTS software fails. Thus, the answer to the question ''What do I need to do or document?'' will be based on the hazard analysis that is an integral part of designing a medical device. The detail of documentation to be provided to FDA and the level of life cycle control necessary for the medical device manufacturer increase as the hazard to the patient from software failure increases.

This draft guidance document lays out in broad terms how the medical device manufacturer should determine what is necessary to do and to document for submission to the agency. A ''BASIC'' set of need-to-do items is proposed for OTS software, and a detailed discussion is provided on additional (''SPECIAL'') needs and responsibilities of the manufacturer when hazards from OTS software failure become more significant.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on use of OTS software in medical devices. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 2 guidance document