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

consistent with GGP's. This draft guidance document was first made available on the internet on June 20, 1997. FDA now believes that it would be useful to make the document more widely available for comment.

III. Electronic Access

In order to receive the draft guidance document ''Off-the-Shelf Software Use In Medical Devices,'' via your fax machine, call the CDRH Facts-On-Demand (FOD) 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 (585) 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). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Off-the-Shelf Software Use In Medical Devices'' 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''.

IV. Comments

Interested persons may, on or before November 16, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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 found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

After November 16, 1998, written comments regarding this draft guidance document may be submitted at any time to the contact person (address above).

Dated: August 4, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–21996 Filed 8–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1998:

Name: Council on Graduate Medical Education.

Date and Time: September 9, 1998, 8:30 a.m.–5:00 p.m.; September 10, 1998, 8:30 a.m.–12:00 p.m.

Place: Holiday Inn, Capital, 550 C Street, S.W., Washington, D.C.

This meeting is open to the public.

Agenda: The agenda will include: opening comments, welcome, and presentations from the Administrator, Health Resources and Services Administration, the Acting Associate Administrator for Health Professions and the Acting Executive Secretary of COGME; a panel on Beyond Medicare: Ambulatory GME Financing; a panel on Innovation and Models in Ambulatory GME Arrangements; and presentations on the Balanced Budget Act and other third-party payers. The Council will discuss ambulatory GME issues. Action will be taken on the GME Policy and Financing Report. Future Council direction will be discussed.

Anyone requiring information regarding the subject should contact F. Lawrence Clare, M.D., M.P.H., Deputy Executive Secretary, telephone (301) 443–6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda items are subject to change as priorities dictate.

Dated: August 11, 1998.

Jane Harrison,

Division of Policy Review and Coordination.

[FR Doc. 98–22000 Filed 8–14–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

ACTION: Notice of receipt of applications.

SUMMARY: The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(a) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

Permit No. PRT—TE 000894–0

Applicant: Sul Ross State University, Department of Biology, Alpine, Texas.

Applicant requests authorization to take 500 Big Bend gambusia (*Gambusia gaigei*) from springs in the vicinity of Rio Grande Village and Boquillas crossing in Big Bend National Park for genetic analysis.

Permit No. PRT—TE000948–0

Applicant: Western New Mexico University, Silver City, New Mexico.

Applicant requests authorization to conduct presence/absence surveys for bald eagles (*Haliaeetus leucocephalus*), peregrine falcons (*Falco peregrinus*), and southwestern willow flycatchers (*Empidonax traillii extimus*) in southwest New Mexico.

Permit No. PRT—814933

Applicant: Texas Parks and Wildlife, Austin, Texas.

Applicant requests authorization to conduct activities for scientific research and recovery purposes for black-capped vireos (*Vireo atricapillus*), Texas blind salamanders (*Typhlomolge rathbuni*), San Marcos salamanders (*Eurycea nana*), Barton Springs salamanders (*Eurycea sosorum*), San Marcos gambusia (*Gambusia georgei*), fountain darter (*Etheostoma fonticola*), Texas wildrice (*Zizania texana*), Comal Springs riffle beetles (*Heterelmis comalensis*), Chisos Mountain hedgehog cactus (*Echinocereus chisoensos*), Lloyd's mariposa cactus (*=Echinomastus (=Echinocactus, =Sclerocactus, =Neolloydia mariposensis*), bunched cory cactus (*Coryphantha ramillosa*), Big Bend gambusia (*Gambusia gaigei*), Clear Creek gambusia (*Gambusia heterochir*), Comanche Springs pupfish (*Cyprinodon elegans*), and Leon Springs pupfish (*Cyprinodon bovinus*).

Permit No. PRT—826091

Applicant: Bureau of Land Management, Phoenix Field Office, Phoenix, Arizona.

Applicant requests authorization to conduct presence/absence surveys and monitoring activities for peregrine falcons (*Falco peregrinus*), Sonoran pronghorn (*Antilocapra americana sonoriensis*), and cactus ferruginous pygmy-owl (*Glaucidium brasilianum cactorum*) on lands administered by the Bureau of Land Management, Phoenix, Arizona.

Permit No. TE001623–0

Applicant: University of New Mexico, Department of Biology, Museum of Southwestern Biology, Albuquerque, New Mexico.

Applicant requests authorization for research and recovery purposes to