available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Persons interested in obtaining a copy of the draft guidance document may do so by using the World Wide Web. FDA's home page address may be accessed at http://www.fda.gov and then select the Medical Devices and Radiological Health option. Next, select the Program Areas option and then select Medical Device Reporting. All Relevant documents will be listed and available for downloading.

Anyone with a video terminal or personal computer with a modem can obtain the draft guidance document from the electronic docket administered by the Division of Small Manufacturers Assistance (1–800–252–1366 or 1–301–594–2741) by making the following menu choices: 5–Postmarket Surveillance; 2–Medical Device Reports—Policies/Guidelines.

Individuals unable to use the above two options may request information, through the CDRH Facts-on-Demand system, about obtaining paper copies of the document, by dialing 1–800–899–0381 or 1–301–827–0111. After following the voice prompts, request document number 799. FDA has arranged to have other government, industry, and health care organizations provide paper copies of the document for a fee that each organization will set for itself.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Safe Medical Devices Act of 1990 (Pub. L. 101–629) (SMDA), on November 26, 1991 (56 FR 60024), FDA issued a tentative final rule proposing to implement regulations requiring user facility and distributor adverse event reporting (hereinafter referred to as the November 1991 tentative final rule). In this November 1991 tentative final rule, FDA also proposed to amend the existing manufacturer reporting regulations to conform to the proposed user facility and distributor reporting requirements.

After FDA's issuance of the November 1991 tentative final rule, the Medical Device Amendments of 1992 (Pub. L. 102–300) (the 1992 amendments) were enacted on June 16, 1992, and amended certain provisions of section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) relating to reporting of adverse device events.

On December 11, 1995 (60 FR 63578), FDA published the MDR regulation for user facilities and manufacturers, based on comments to the November 1991 tentative final rule. In the Federal Register of April 11, 1996 (61 FR 16043), the effective date of this final rule was extended to July 31, 1996, in order to provide additional time for compliance. The requirements for manufacturer and user facility reporting are found at 21 CFR part 803.

II. Draft Guidance for Manufacturers

Due to the diversity and complexity of medical device products, no regulation could address each possible reporting scenario. Therefore, the agency is providing additional guidance to the industry. The agency has developed a draft guidance document entitled ''Medical Device Reporting for Manufacturers.'' This draft guidance contains information describing: Who is covered by the MDR rule, who is responsible for reporting, how to report, and when to report. The draft guidance also contains statements of FDA policy, interpretations of the regulation, and answers to frequently asked questions. The agency also addresses in this guidance, many questions which have been raised after to the publication of the November 1991 tentative final rule. However, because the agency anticipates that additional new questions and issues may be raised as the effective date of the MDR regulation approaches, the agency is issuing the manufacturer guidance as a draft document and specifically invites questions and comments on matters not already addressed in the draft guidance. The agency will consider all submitted comments when revising the draft guidance. The agency anticipates that a revised guidance document for manufacturers will be available by November 27, 1996. In the interim, FDA believes the information contained in the draft guidance will be useful to medical device manufacturers as they seek to implement the requirements of the new MDR final rule.

III. Significance of a Guidance

A guidance document does not bind FDA or the public, and does not create or confer any rights, privileges, or benefits for or on any person; however, it does represent the agency's current thinking on the subjects discussed therein. The draft guidance document announced in this notice represents the agency's tentative thinking on issues related to manufacturer reporting.

IV. Request for Comments

Interested persons may, on or before August 29, 1996, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance entitled ''Medical Device Reporting for Manufacturers.'' Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified by the title of the guidance and the docket number found in brackets in the heading of this document. Copies of the guidance documents and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in revising the draft guidance document.

Dated: May 21, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–13665 Filed 5–30–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: June 12, 1996.

Time: 6 p.m.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Michael D. Hirsch, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301, 443–1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: June 14, 1996.

Time: 12 p.m.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Michael D. Hirsch, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301, 443–1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: June 20, 1996.

Time: 8;30 a.m.

Place: The Latham Hotel Georgetown, 3000 M Street, NW., Washington, DC 2007.

Contact Person: Phyllis D. Artis, Parklawn Building, Room 9C–26, 5600 Fishers Lane,

Rockville, MD 20857. Telephone: 301, 443–6470.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: May 22, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–13660 Filed 5–30–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–3778–N–87]

Office of the Assistant Secretary for Community Planning and Development; Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

DATES: May 31, 1996.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street, SW, Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-fee), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: May 23, 1996.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 96–13480 Filed 5–30–96; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of the Final Joint Programmatic Environmental Impact Report and Environmental Impact Statement on the Proposed Issuance of Incidental Take Permits for the Coastal California Gnatcatcher and Six Other Listed Species in the Central and Coastal Natural Community Conservation Planning Subregion of Orange County, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: This notice advises the public that the Final Environmental Impact Report/Environmental Impact Statement (EIR/EIS) on the proposed issuance of nine incidental take permits for seven listed species in the Central and Coastal Natural Community Conservation Planning (NCCP) Subregion of Orange County, California, is available. Publication of the Record of Decision and issuance of the permits will occur no sooner than 30 days from the date of this notice. This notice is provided pursuant to regulations implementing the National Environmental Policy Act (40 CFR 1506.6).

ADDRESSES: The documents discussed herein are available for public inspection, by appointment, during normal business hours, at the Carlsbad Field Office, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008 (telephone: 619–431–9440); and at the Planning Department, Orange County Environmental Management Agency, 300 North Flower Street, Santa Ana, California 92702 (telephone: 714–834–5550).

FOR FURTHER INFORMATION CONTACT: Mr. Gail Kobetich, Field Supervisor, U.S. Fish and Wildlife Service (see **ADDRESSES** above), telephone: 619–431–9440; or Mr. Tim Neely, Planning and Zoning Administrator, Orange County Environmental Management Agency (see **ADDRESSES** above), telephone: 714–834–2552.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Copies of the Final EIR/EIS and associated documents (comment letters on the Draft EIS/EIR, response to comments, the final Implementation Agreement, and final maps) can be obtained by contacting the Carlsbad or Santa Ana offices listed above (see **ADDRESSES**). The response to comments addresses changes that were made in draft documents associated with the permit applications that previously were made available for public review. The complete application file may be viewed during normal business hours, by appointment, at the Carlsbad and Santa Ana offices. A letter announcing availability of the Final EIR/EIS has been forwarded to all parties who previously received the notice of availability of the Draft EIR/EIS, and/or who requested a copy of, or commented on, the Draft EIR/EIS.

Background

On March 30, 1993, the U.S. Fish and Wildlife Service (Service) published a final rule determining the coastal California gnatcatcher (*Polioptila californica californica*) as a threatened species (58 FR 16742). The ''take'' of threatened and endangered species is prohibited under section 9 of the Act and its implementing regulations. Take is defined in part as killing, harming or harassing listed species, including significant habitat modification that kills or injures listed species. The Service, however, may issue permits under section 10 of the Act to conduct activities involving the take of threatened and endangered species under certain circumstances, including carrying out scientific activities, enhancing the propagation or survival of the species, or incidentally taking the species in connection with otherwise lawful activities. Regulations governing such permits are at 50 CFR 17.22 and 17.32.

On December 10, 1993, the Service issued a final special rule for the coastal California gnatcatcher, pursuant to section 4(d) of the Act (58 FR 65088). Incidental take of the gnatcatcher is allowed under the special rule if such take results from activities conducted under a plan prepared pursuant to the NCCP Act of 1991, NCCP Process Guidelines, and the NCCP Southern California Coastal Sage Scrub Conservation Guidelines. The special rule also requires Federal approval of the NCCP Plan/Habitat Conservation Plan (HCP).

The County of Orange (lead applicant), University of California-