and 640.63(c)); (2) failure to investigate donor adverse reactions (21 CFR 606.170(a)); (3) failure to perform adequate donor physical examinations (21 CFR 640.63(b)(3) and 640.63(c)(9)); (4) failure to provide suitable facilities (21 CFR 606.40(a)(1)); (5) failure to perform and maintain records of quality control for equipment and reagents (21 CFR 606.60(a), 606.160(b)(5)(i), and 606.160(b)(7)(iv)); and (6) failure to maintain complete and accurate records and follow standard operating procedures (21 CFR 606.160(b)(1)(i), 606.160(b)(1)(ii), and 640.65(b)(3)).

Accordingly, due to the serious nature of the deviations, which the Commissioner of Food and Drugs determined to constitute a danger to health, FDA suspended the firm's licenses by letter dated January 11, 1994. In a letter to FDA dated January 20, 1994, Plascon, Inc., requested that revocation be held in abeyance and that a time extension be granted by which another corrective action plan would be submitted. By letter dated January 27, 1994, FDA granted the request for a time extension to submit in writing the corrective action plan. By letter dated January 28, 1994, Plascon, Inc., requested a second time extension for submission of the plan. By letter dated, February 10, 1994, FDA granted the second time extension. By letter dated February 21, 1994, Plascon, Inc., submitted the corrective action plan to FDA.

After consideration of Plascon, Inc.'s, submission, FDA sent a letter dated May 5, 1994, denying Plascon, Inc.'s, request that the license revocation be held in abeyance. FDA advised Plascon, Inc., that the most recent corrective action plan was incomplete and inadequate, and that Plascon, Inc.'s, claim that sufficient corrective actions would be implemented and sustained was not credible in light of the firm's careless disregard of the applicable regulations and standards. In accordance with § 601.5(b) (21 CFR 601.5(b)), FDA advised Plascon, Inc., that no additional time would be provided in which to demonstrate compliance with the regulations and standards before FDA would initiate proceedings to revoke Plascon, Inc.'s, licenses. Plascon, Inc., was offered the option of voluntarily requesting that the licenses be revoked. Plascon, Inc., was further advised that, should that option not be exercised, FDA would initiate proceedings to revoke the license by publishing in the Federal Register a notice of opportunity for a hearing on a proposal to revoke the licenses, pursuant to § 12.21(b) (21 CFR 12.21(b)), as provided in § 601.5(b). Plascon, Inc., did not respond to FDA's letter within the specified response period.

Thus, under § 12.21(b), FDA is issuing a notice of opportunity for a hearing on a proposal to revoke Plascon, Inc.'s, licenses. FDA has placed copies of letters between FDA and Plascon, Inc., concerned with the revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) November 12, 1992, warning letter from FDA to Plascon, Inc.; (2) January 6, 1993, response letter from Plascon, Inc., to FDA regarding FDA inspectional findings of inspection conducted between August 11, 1992, and October 21, 1992; (3) January 7, 1994, response letter from Plascon, Inc., to FDA regarding FDA inspectional findings of inspection conducted between December 13, 1993, and December 17, 1993; (4) January 11, 1994, letter from FDA to Plascon, Inc., suspending the firm's licenses; (5) January 20, 1994, letter from Plascon, Inc., to FDA requesting that license revocation be held in abeyance and that an extension of time be granted to submit another corrective action plan; (6) January 27, 1994, letter from FDA granting the request for an extension of time to submit in writing a corrective action plan; (7) January 28, 1994, letter from Plascon, Inc., requesting a second extension of time for submission of a corrective action plan; (8) February 10, 1994, letter from FDA to Plascon, Inc., granting the second extension of time; (9) February 21, 1994, letter from Plascon, Inc., submitting a corrective action plan to FDA; and (10) May 5, 1994, letter from FDA to Plascon, Inc., denying the firm's request that the revocation be held in abeyance and advising Plascon, Inc., that the corrective action plan submitted by letter dated February 21, 1994, was incomplete and inadequate and that FDA would institute license revocation proceedings. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Plascon, Inc., may submit a written request for a hearing to the Dockets Management Branch by December 18, 1995, and any data and information justifying a hearing must be submitted by Janaury 16, 1996. Other interested persons may submit comments on the proposed revocation by January 16, 1996.

FDA procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on a proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is not genuine and substantial issue of fact for resolution at a hearing, or if a request for a hearing is not made within the specified time, or in the required format or the required analyses, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act (sec. 351 (42 U.S.C. 262)) and the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 505, 701 (21 U.S.C. 321, 351, 352, 355, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: November 8, 1995.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 95–28367 Filed 11–16–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Peripheral and Central Nervous System Drugs Advisory Committee

Date, time, and place. December 4, 1995, 8:30 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4 p.m.; William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, Michael A. Bernstein, Center for Drug Evaluation and Research (HFD–120), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–594–5521, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Peripheral and Central Nervous System Drugs Advisory Committee, code 12543.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in neurological disease.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before November 28, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss product license application 95–0979 from Biogen, Inc., for Interferon Beta-1a (Avonex™), for treatment of relapsing forms of multiple sclerosis.

Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee

Date, time, and place. December 4 and 5, 1995, 8:30 a.m., DoubleTree Hotel, Conference Center, Rockville, MD.

Type of meeting and contact person. Open public hearing, December 4, 1995, 8:30 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 5:30 p.m.; open public hearing, December 5, 1995, 8:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 4 p.m.; Jeanne L. Rippere or Stephanie A. Mason, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–1003, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Dental Products Panel of the Medical Devices Advisory Committee, code 12518.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

The Dental Products Panel of the Medical Devices Advisory Committee functions at times as a nonprescription drug advisory panel. As such, the panel reviews and evaluates available data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed nonprescription drug products for human use, the adequacy of their labeling, and advises the Commissioner of Food and Drugs on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on the general issues pending before the subcommittee. Those desiring to make formal presentations should notify the contact person before November 24, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On December 4, 1995, the subcommittee will discuss data and information submitted to support the safety and effectiveness of hydrogen peroxide, sodium bicarbonate, and a combination of these two ingredients for use in the prevention and/or treatment of dental plaque and gingivitis. On December 5, 1995, if necessary, the subcommittee will continue its discussion of hydrogen peroxide and sodium bicarbonate. In addition, it will begin to discuss data and information submitted to support the safety and effectiveness of sanguinaria extract for use in the prevention and/or treatment of dental plaque and gingivitis.

Dermatologic and Ophthalmic Drugs Advisory Committee Subcommittee on Ophthalmic Drugs With Representation From the Antiviral Drugs Advisory Committee

Date, time, and place. December 8, 1995, 8:30 a.m., Holiday Inn—Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m., Ermona B. McGoodwin or Valerie M. Mealy, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Dermatologic and Ophthalmic Drugs Advisory Committee, code 12534.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 1, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the

approximate time required to make their comments.

Open committee discussion. The committee will discuss data relevant to the new drug application (NDA) 20–569 ganciclovir intravitreal implant (Vitrasert® Sterile Intravitreal Implant, Chiron Vision Corp.) for treatment of cytomegalovirus retinitis. The committee will also discuss data relevant to NDA 20–597 latanoprost (Xalatan™ Sterile Ophthalmic Solution, Pharmacia, Inc.) a topical ophthalmic drug indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma and ocular hypertension.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: November 13, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–28366 Filed 11–16–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. FR–3778–N–63]

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.

EFFECTIVE DATE: November 17, 1995.

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-free), 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: November 9, 1995.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 95–2828 Filed 11–16–95; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of a Draft Environmental Impact Statement and Receipt of an Application for the Proposed Issuance of a Permit To Allow Incidental Take of Threatened and Endangered Species on Plum Creek Timber Company, L.P., Lands in the I–90 Corridor, King and Kittitas Counties, WA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability; request for comments.

SUMMARY: This notice advises the public that Plum Creek Timber Company, L.P. (Applicant) has applied to the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together Services) for an incidental take permit pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act). The Applicant has also requested unlisted-species and safe-harbor provisions in an Implementation Agreement (Agreement) to cover vertebrate species which may be found in the planning area. The application has been assigned permit number PRT–808398. The requested permit would