information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: August 7, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–20963 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0131]

''Point to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals (1995);'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a points to consider (PTC) document entitled, ''Points to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals (1995).'' The PTC document is intended to assist manufacturers in the production of safe, pure, potent, and effective therapeutic products for human use that are derived from transgenic animals. The PTC document is also intended to help sponsors assure the quality and consistency of data submitted in connection with an investigational new drug application (IND), product license application (PLA), establishment license application (ELA) or new drug application (NDA).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the PTC document to the Congressional and Consumer Affairs Branch (HFM–12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to the INTERNET may request this document from ''CBER INFO@A1.CBER.FDA.GOV.'' The document may also be obtained by calling the CBER FAX Information System at 301–594–1939 from a FAX machine with a touch tone phone attached or built in. Submit written comments on the PTC document to the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the PTC document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Timothy Beth, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a PTC document entitled ''Points to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals (1995).'' The PTC document provides a discussion of issues that should be considered in the development of therapeutic products derived from transgenic animals. A transgenic animal is an animal with an altered genome produced by introduction of deoxyribonucleic acid (DNA) through human intervention. The PTC document addresses issues such as the structure of the gene product, the fidelity of inheritance, the consistency of expression, and the avoidance of contamination by drugs, chemicals, and adventitious agents. Specific topics discussed in the PTC document include: (1) Generation and characterization of the transgene constructs; (2) creation and characterization of the transgenic founder animal; (3) establishment of a reliable and continuous source of transgenic animals; (4) generation and selection of production herds; (5) maintenance of transgenic animals; (6) purification and characterization of the transgenic product; (7) analysis of product quality; and (8) preclinical safety evaluation. The PTC document contains a reference section that lists laws, regulations, guidances, guidelines, PTC's and policies which may be applicable and should be considered when manufacturing therapeutic products for human use from transgenic animals.

As with other PTC documents, FDA does not intend this PTC document to be all-inclusive and cautions that not all information may be applicable to all situations. The PTC document is intended to provide information and does not set forth requirements. The methods and procedures cited in the PTC document are suggestions. FDA anticipates that sponsors and investigators may develop alternative methods and procedures, and discuss them with FDA. FDA may find those alternative methods and procedures acceptable. FDA recognizes that advances will continue in the area of human therapeutic products derived from transgenic animals and that this document may become outdated as those advances occur. The PTC document does not bind FDA and does not create or confer any rights, privileges, or benefits on or for any person, but is intended merely for guidance.

FDA is making available the PTC document in association with its responsibility to regulate drugs, medical devices, and biological products intended for human use. The PTC document is neither a regulation nor a guideline, but is an FDA compilation of information and suggestions on the subject of manufacturing therapeutic products for human use derived from transgenic animals. All applicable Federal laws and regulations must be followed and adhered to when manufacturing therapeutics for human use.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the PTC document. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether further revision of the PTC document is warranted.

Dated: August 17, 1995.

William K. Hubbard,

Deputy Commissioner for Policy.

[FR Doc. 95–20964 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the

meetings 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.

MEETINGS: The following advisory committee meetings are announced:

Device Good Manufacturing Practice Advisory Committee

Date, time, and place. September 13 and 14, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA committee meeting block of rooms. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Regenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, September 13, 1995, 8:30 a.m. to 2:30 p.m., unless public participation does not last that long; open committee discussion, 2:30 p.m. to 4:30 p.m.; open committee discussion, September 14, 1995, 8:30 a.m. to 4:30 p.m.; Sharon M. Kalokerinos, Center for Devices and Radiological Health (HFZ–331), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4613, ext. 139, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Device Good Manufacturing Practice Advisory Committee, code 12398.

General function of the committee. The committee reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

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 August 30, 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 consider the tentative final rule on quality systems which sets forth requirements for current good manufacturing practices to include methods used in, and the facilities and controls used for the design, purchasing, manufacturing, packaging, labeling, storage, installation, and servicing of all finished medical devices intended for human use. This document was made available through a Notice of Availability published on July 24, 1995 (60 FR 37856), and copies can be obtained from the Division of Small Manufacturers Assistance (HFZ–220), Food and Drug Administration, 1350 Piccard Dr. Rockville, MD 20850.

Peripheral and Central Nervous System Drugs Advisory Committee

Date, time, and place. September 18, 1995, 8:30 a.m., Parklawn Bldg., conference rooms G through J, 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 5 p.m.; Michael A. Bernstein, Center for Drug Evaluation and Research (HFD–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2775, 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 September 11, 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 the safety and effectiveness of Rilutek® (riluzole), new drug application (NDA) 20–599, Rhone-Poulenc Rorer Pharmaceuticals, Inc., for use in the treatment of Amyotrophic Lateral Sclerosis (ALS).

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. September 25, 1995, 8 a.m., Parklawn Bldg., conference rooms G through J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Leander B. Madoo, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Pulmonary-Allergy Drugs Advisory Committee, code 12545.

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 the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

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 September 25, 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 two NDA's: (1)

NDA 20–548, Flovent™ Inhalation Aerosol (a metered-dose inhaler formulation of fluticasone propionate), and (2) NDA 20–549, Flovent™ Inhalation via Diskhaler (a dry powder formulation of fluticasone propionate). Both NDA's are indicated for the maintenance treatment of bronchial asthma and for treatment of patients requiring oral corticosteroid therapy for asthma who may be able to significantly reduce or eliminate their requirement for oral corticosteroids over time. The sponsor for both NDA's is Glaxo Welcome.

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. September 28, 1995, 8 a.m., Parklawn Bldg., conference rooms G through J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Kathleen R. Reedy, Center for Drug Evaluation and Research, Advisors and Consultants Staff (HFD–9), 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), Endocrinologic and Metabolic Drugs Advisory Committee, code 12536.

General function of committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic 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 September 21, 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 hear presentations and discuss data submitted regarding the safety and efficacy of dexfenfluramine hydrochloride, NDA 20–344, Interneuron Pharmaceuticals, Inc., for an obesity indication.

Joint Meeting of the Drug Abuse Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. September 29, 1995, 9 a.m., Parklawn Bldg., conference rooms G through J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; Stephen P. Pollitt or Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD–9), 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), Drug Abuse Advisory Committee, code 12535.

General function of the committee. The Drug Abuse Advisory Committee advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs, and recommends actions to be taken on the marketing, investigation, and control of such drugs. The Endocrinologic and Metabolic Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic 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 September 18, 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 committees will discuss the petition to remove from the Controlled Substance Act, Fenfluramine and its isomers, Fenfluramine, NDA 16–618, Wyeth-Ayerst, and Dexfenfluramine, NDA 20–344, Interneuron Pharmaceuticals Inc.

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: August 17, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–21001 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

Pesticide Residue Monitoring Data Base for Fiscal Year 1994; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of Fiscal Year (FY) 1994 pesticide residue monitoring data on computer diskettes. This is the third annual comprehensive compilation and public release of FDA monitoring data for pesticide residues in foods. The agency is making the information available on computer diskettes to facilitate its dissemination to interested persons.

ADDRESSES: Pesticide residue monitoring data on computer diskettes may be ordered from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield VA 22161. Orders must reference NTIS order number PB95–503132 and include a payment of $50.00 for each copy of the data base. In addition, there is a handling fee of $4.00 for one copy of the data base, $6.00 for two copies, and $8.00 for three or more copies. Payment may be made by check, money order, charge card (American Express, VISA, or MasterCard), or by billing arrangements made with NTIS. Charge card orders must include the charge account number and expiration date. For telephone orders or further information on placing an order call NTIS at 703–487–4650.

FOR FURTHER INFORMATION CONTACT: Marcia G. Houston, Center for Food Safety and Applied Nutrition (HFS–308), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4152.

SUPPLEMENTARY INFORMATION: FDA is making available its FY 94 pesticide residue monitoring data as a set of three personal computer diskettes. The data base includes FDA pesticide monitoring coverage and findings for FY 94 by country/food product/pesticide combination. The data base is accompanied by a search program and report formats, written in dBase III+. Each year FDA receives numerous requests for these data. FDA has determined that it will facilitate dissemination of these data to interested persons if the agency provides for their general availability in a standardized diskette. A user's manual is provided that contains installation instructions and describes the structure and content of the data base.

Dated: August 16, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–20961 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Meeting

Notice is hereby given of the meeting of the NIH AIDS Research Program Evaluation Working Group on September 13, 1995, at the Omni Shoreham Hotel, 2500 Calvert Street NW., Washington, DC, from 8:30 am to 5 pm. The meeting will be open to the public from 10:30 am to 5 pm with attendance limited to space available.

The purpose of the meeting is to review the status of each of the six Area Review Panels through presentations from the Area Review Panel Chairs and to obtain input from the infected and affected community. The NIH AIDS Research Program Evaluation Working Group will develop recommendations to be made to the Office of AIDS Research Advisory Council that address the overall NIH AIDS research initiative, both intramural and extramural, and identify long-range goals in the relevant areas of science. These recommendations will provide the framework for future planning and budget development of the NIH AIDS research program.

The 10:30 am to 12:30 pm session of the meeting will be for presentations from designated participants. The 1 pm to 5 pm session will be for public presentations. Those desiring to make formal presentations at the public session should notify Dr. Robert Eisinger, Office of AIDS Research, National Institutes of Health, 31 Center Drive, MSC 2340, Building 31, room 4B62, Bethesda, MD 20892–2340, (301) 402–8655 before September 8, 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. Interested persons may present data, information, or views in writing on issues pending before the Working Group.

There will be a closed session from 8:30 am to 10:30 am to update the Working Group members on privileged information from the Area Review Panels on institute and center grant and contract portfolios.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Eisinger in advance of the meeting.

Dated: August 18, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–20987 Filed 8–24–95; 8:45 am]

BILLING CODE 4140–01–M

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board and the Center for Substance Abuse Prevention (CSAP) National Advisory Council in September 1995.

The meeting of the CSAP Drug Testing Advisory Board will include discussion of announcements and reports of administrative, legislative, and program developments. It will also include reviews of sensitive National Laboratory Certification Program (NLCP) internal operating procedures and program development issues. Therefore, a portion of this meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(2), (4), and (6) and 5 U.S.C. Appendix 2, section 10(d).

Committee Name: Drug Testing Advisory Board.

Meeting Date(s): September 20, 1995.

Place: DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20857.

Open: September 20, 1995, 8:30 a.m.–10:00 a.m.

Closed: September 20, 1995, 10:00 a.m.–Adjournment.

Contact: Donna M. Bush, Ph.D.; Parklawn Building, room 13A–54; Telephone: (301) 443–6014.