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