decisions regarding the AHCPR-sponsored guideline are made.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Ms. Gray by October 10, 1995, at the address below.

Registration should be made with, and written materials submitted to: Becky Gray, Duke University, First Union Tower, 2200 West Main Street, Suite 230, Durham, North Carolina 27705, Phone: (919) 286–3399, Fax: (919) 286–5601.

For Additional Information

Additional information on the guideline development process is contained in the AHCPR Program Note, ''Clinical Practice Guideline Development,'' dated August 1993. This document describes AHCPR's activities with respect to clinical practice guidelines including the process and criteria for selecting panels. This document may be obtained from the AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907; or call Toll-Free: 1–800–358–9295.

Also, information can be obtained by contacting Douglas B. Kamerow, M.D., M.P.H., Director, Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, Willco Building, 6000 Executive Boulevard, Suite 310, Rockville, MD 20852, Phone 301–594–4015, Fax: 301–594–4027.

Dated: August 18, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–21000 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–90–M

Centers for Disease Control and Prevention (CDC)

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC), Announces the Following Meeting

Name: Annual Meeting of CDC-Funded Childhood Blood Lead Surveillance Cooperative Agreement and Grant Recipients.

Times and Dates: 8:30 a.m.–5 p.m., September 6, 1995; 8:30 a.m.–5 p.m., September 7, 1995; 8:30 a.m.–3 p.m., September 8, 1995.

Place: Terrace Garden Inn-Buckhead, 3405 Lenox Road, NE, Atlanta, Georgia 30326.

Status: Open to the public, limited only by space available.

Purpose: The primary purpose of this meeting is to provide a forum for the recipients of CDC-Funded Childhood Blood Lead Surveillance Cooperative Agreement and Grant funds to review program progress and discuss surveillance issues and concerns.

Matters to be Discussed: Topics will include discussions on CDC childhood lead surveillance activities, CDC Lead Poisoning Prevention Branch and laboratory activities, core variables for laboratory reporting, data use by State health departments to direct prevention activities, data mapping, software demonstrations, and use of bar coding technology to transfer data.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Carol A. Pertowski, M.D., Medical Epidemiologist, Surveillance and Programs Branch, Division of Environmental Hazards and Health Effects (F42), NCEH, CDC, 4770 Buford Highway, NE, Atlanta, Georgia 30341–3724, telephone 404/488–7330, FAX 404/488–7330.

Written comments are welcome and should be received by August 31, 1995. Persons wishing to make oral comments at the meeting should notify the contact person in writing or by telephone no later than close of business on August 31, 1995. All requests to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. Depending on the time available and the number of requests to make oral comments, it may be necessary to limit each presenter.

Dated: August 17, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–20992 Filed 8–23–95; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95N–0264]

Drug Export; Bulk Codeine Contin® Granulation (100 milligrams (mg), 150 mg, 200 mg)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Purdue Frederick Co. has filed an application requesting approval for the export of the human drug Bulk Codeine Contin® granulation to Canada for tablet compression, labeling, and packaging into 100–, 150–, and 200–milligram (mg) controlled release tablets.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that The Purdue Frederick Co., 100 Connecticut Ave., Norwalk, CT 06850, has filed an application requesting approval for the export of the human drug Bulk Codeine Contin® granulation to Canada for tablet compression, labeling, and packaging into 100–, 150–, and 200–mg controlled release tablets. Bulk Codeine Contin® granulation is used for the relief of mild to moderate pain requiring the prolonged use of an opioid analgesic preparation. The application was received and filed in the Center for Drug Evaluation and Research on August 2, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 5, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the

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