ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.'' This draft guidance is intended to provide recommendations to sponsors and applicants of new drug applications (NDA's) and biologics license applications (BLA's) for therapeutic biologics (hereafter drugs) on carrying out in vivo drug metabolism and metabolic drug-drug interaction studies. The draft guidance reflects the current view that the metabolism of a new drug should be defined during drug development and that its interactions with other drugs should be explored as part of an adequate assessment of the safety and effectiveness of the drug.

DATES: Written comments may be submitted on the draft guidance by January 19, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of ''In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling'' are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, FAX 888–CBERFAX or 301–827–3844. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Shiew Mei Huang, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5671, or David Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.'' Previous guidance from FDA on the use of in vitro approaches to study metabolism and metabolic drug-drug interactions is available in a document entitled ''Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies in Vitro.'' The present guidance should be viewed as a companion to this earlier guidance. The present guidance discusses study design, choice of interacting drugs, and data analysis and provides recommendations for dosing and labeling.

This draft level 1 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on drug metabolism and drug-drug interactions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30937 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0997]

Draft Guidance for Industry on Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation.'' This draft document provides guidance for industry on the chemistry, manufacturing, and controls (CMC) documentation to be submitted in new drug applications (NDA's) and abbreviated new drug applications (ANDA's) for metered dose inhalation aerosols, metered dose nasal aerosols, and inhalation powders.

DATES: Written comments may be submitted on the draft guidance document by February 17, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm.'' Written requests for single copies of the draft guidance should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Guirag Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, rm. 10B45, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance sets forth information that should be provided to ensure continuing drug product quality and performance characteristics for MDI's and DPI's. In addition to providing guidance on CMC documentation to be submitted in NDA's and ANDA's for DPI's and MDI's, the draft guidance covers CMC information recommended for inclusion in the application with regard to the components, manufacturing process, and the controls associated with each of these areas. The document does not address inhalation solutions or aqueous nasal sprays.

FDA intends to sponsor a public meeting in 1999 on MDI and DPI drug products. The comments submitted on

this draft guidance will be used to help develop the agenda for this meeting.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on CMC documentation to be submitted in NDA's and ANDA's for metered dose inhalation aerosols, metered dose nasal aerosols, and inhalation powders. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30938 Filed 11–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Supplemental Grant Award to the National Research and Training Center at the University of Illinois, Chicago, IL

AGENCY: Center for Mental Health Services (CMHS), Substance Abuse and Mental Health Services Administration (SAMHSA), DHHS.

ACTION: Planned supplemental grant award to the Employment Intervention Demonstration Program (EIDP) Coordinating Center at the University of Illinois, Chicago, Illinois.

SUMMARY: This notice is to provide information to the public concerning a planned supplemental award by CMHS/SAMHSA to the existing grant to the National Research and Training Center (NRTC). This award will provide additional support for the EIDP Coordinating Center in order to expand coordination, data management, and dissemination of the EIDP study results. Upon receipt of a satisfactory application that is recommended for approval by an Initial Review Group and the CMHS National Advisory Council, up to $600,000 in Federal funds may be awarded to this organization over the remaining project period of the existing EIDP Coordinating Center grant which is scheduled to end on May 31, 2000.

This is not a formal request for applications. Grant funds will be provided only to the organization named above.

Authority/Justification: This grant will be made under the authority of Section 520A of the Public Health Service Act, as amended (42 U.S.C. 290bb–32).

The Catalog of Federal Domestic Assistance (CFDA) number is 93.125.

The goal of the EIDP is the generation of knowledge about effective approaches for enhancing employment for adults with severe mental illnesses through support for the implementation and evaluation of promising employment intervention programs. In FY 1995 the National Research and Training Center competed successfully to be the Coordinating Center for an expected EIDP involving approximately 4 sites. However, CMHS subsequently determined the program should fund 8 sites to maximize the potential benefits of the program. The purpose of this supplemental award is to fund the additional coordination and data management requirements imposed on NRTC for a program which has expanded to 8 sites and, building upon the expertise gained by the Coordinating Center during the first years of the study, to develop and implement a knowledge dissemination strategy for all 8 (rather than 4) sites. The supplemental work is inextricably linked to the current activities that the NRTC is already performing for the EIDP.

For the above reasons, only an application from the National Research and Training Center will be considered for this program.

CONTACT: Neal B. Brown, Chief, Community Support Programs Branch, Division of Knowledge Development and Systems Change, CMHS, SAMHSA, 5600 Fishers Lane, Room 11C–22, Rockville, MD 20857; (301) 443–3653.

Dated: November 13, 1998.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 98–30940 Filed 11–18–98; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of a meeting of the Center for Mental Health Services (CMHS) National Advisory Council in December, 1998.

A portion of the meeting will be open and will include a roll call, CMHS Director's Report, discussion of the HIV/AIDS Services Research Demonstration Program, report from the National Mental Health Association, update from the Consumer Affairs Specialist and a report on Mental Health U.S. 1998. Public comments are welcome during the open session. Please communicate with the individual listed as contact below for guidance. If anyone needs special accommodations for persons with disabilities please notify the contact listed below.

The meeting will include the review, discussion, and evaluation of individual grant applications, and detailed discussion of information about the CMHS procurement plans. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(3), and (6) and 5 U.S.C. App. 2, § 10(d).

A summary of the meeting and a roster of Council members may be obtained from: Anne Mathews-Younes, Ed.D., Executive Secretary, CMHS National Advisory Council, 5600 Fishers Lane, Room 18 C–07, Rockville, Maryland 20857. Telephone: (301) 443–0554.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Center for Mental Health Services National Advisory Council.

Meeting Date: December 3–4, 1998.

Place: Georgetown University Conference Center, 3800 Reservoir Road, NW, Washington, D.C. 20057.

Open: December 3, 1998, 9:30 a.m.—5:00 p.m.; December 4, 1998, 9:00 a.m—1:00 p.m.

Closed: December 3, 1998, 9:00 a.m. to 9:30 a.m.

Contact: Anne Mathews-Younes, Room 18–07, Parklawn Building, Telephone: (301) 443–0554 and FAX: (301) 443–7912.