FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss FDA oversight of the Mammography Quality Standards Act (the MQSA) inspectors and inspections, the MQSA compliance guidance, and FDA's role under the MQSA in evaluating personnel competency. The committee will also receive updates on the status of accreditation and certification of full field digital mammography, use of small field digital mammography receptors for diagnostic examinations, States as certification agencies under the MQSA, and the Inspection Demonstration Project. The MQSA compliance guidance documents, which are in a question-and-answer format, are available to the public on the Internet at http://www.fda.gov/cdrh/mammography. This guidance is being updated continually in response to questions that FDA receives from the public. Additional information regarding guidance updates may be obtained by calling the Information Line.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 1, 2000. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on September 28, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 1, 2000, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 2, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–20342 Filed 8–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1392]

Draft Guidance for Industry on Botanical Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Botanical Drug Products.'' This draft guidance explains the circumstances under which FDA approval of a new drug application (NDA) is required for marketing of a botanical drug product and when such a product may be marketed under an over-the-counter (OTC) drug monograph. It also provides guidance to researchers and manufacturers on conducting initial and expanded clinical investigations of botanical drug products. After evaluating the comments it receives, FDA will issue this guidance in final form to encourage the submission of investigational new drug applications (IND's) for botanical drugs.

DATES: Submit written comments on the draft guidance by October 10, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your request. 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. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Yuan-yuan Chiu, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5918.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Botanical Drug Products.'' Botanical products are finished, labeled products that contain vegetable matter, which may include plant material, algae, macroscopic fungi, or combinations of these substances. Botanical products may be intended for use as drugs, foods (including dietary supplements), or cosmetics.

This guidance is intended to encourage the clinical study and submission for marketing approval of botanical drug products. The guidance explains the circumstances under which FDA approval of an NDA is required for marketing a botanical drug and when such a drug may be marketed under an OTC drug monograph. The draft also provides scientific and regulatory guidance to sponsors about conducting initial and expanded clinical investigations of botanical drugs, including those botanical products currently lawfully marketed as foods and dietary supplements in the United States. In particular, the guidance provides information on how the agency will interpret and apply to botanical drugs certain provisions of existing regulations on the submission of IND's (21 CFR part 312).

This level 1 draft guidance is being issued in accordance with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the development of botanical drug products. 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 statutes, regulations, or both.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by October 10, 2000. 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: July 31, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–20343 Filed 8–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of a meeting of the Advisory Committee to the Director, NIH.

The entire meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting. The meeting will take place via conference call with the members. A speaker phone will be installed in the conference room for the public to listen to the discussion.

Name of Committee: Advisory Committee to the Director, NIH.

Date: September 14, 2000.

Time: 4–5 p.m.

Agenda: To discuss and provide advice on the final Report from the Working Group on NIH Oversight of Clinical Gene Transfer Research.

Place: National Institutes of Health, 1 Center Drive, Building 1, Room 151, Bethesda, Maryland 20892.

Contact: Ms. Janice C. Ramsden, Special Assistant to the Principal Deputy Director, NIH, National Institutes of Health, Building 1, Room 235, Bethesda, Maryland 20892, *jr52h@nih.gov*, Telephone: (301) 496–0959.

Dated: August 4, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–20371 Filed 8–10–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute (NCI); Rational Design of Hepatocyte Growth Factor (HGF) Agonists and Antagonists

An opportunity for a Cooperative Research and Development Agreement (CRADA) is available for collaboration with the NCI intramural Structural Biophysics Laboratory 9SBL) to rationally design agonists and antagonists to hepatocyte growth factor (HGF). Collaborative projects will focus upon cancer and/or areas of infectious diseases of high public health significance and high national and international priority.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of an opportunity for Cooperative Research and Development Agreement (CRADA).

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks one Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company to rationally design agonists and antagonists to hepatocyte growth factor (HGF). The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, methods of treatment or prevention that may result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA and which are the subject of the CRADA Research Plan.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Jeffrey W. Thomas, Technology Development and Commercialization Branch, National Cancer Institute-Frederick Cancer Research and Development Center, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301–846–5465; fax: 301–846–6820; e-mail: jeffreyt@mail.nih.gov).

Scientific inquiries should be submitted to Dr. R. Andrew Byrd, Chief, Structural Biophysics Laboratory, National Cancer Institute-Frederick Cancer Research and Development Center, Bldg. 538, Room 120, Frederick, MD 21702–1201 (phone: 301–846–1407; Fax: 301–846–6231; e-mail rabyrd@ncifcrf.gov).

EFFECTIVE DATE: Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential, preliminary CRADA proposals, preferably two pages or less, must be submitted to the NCI on or before September 11, 2000. Guidelines for preparing final CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will be have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

The Structural Biophysics Laboratory, DBS, NCI is seeking a collaborative partner to pursue the rational design of hepatocyte growth factor (HGF) agonists and antagonists. HGF is a secreted, heparin-binding protein that stimulates mitogenesis, motogenesis, and morphogenesis in a wide spectrum of cellular targets including epithelial, endothelial, and hematopoietic cells, as well as hepatocytes. HGF and its receptor, c-Met, are essential for embryonic development, and HGF signaling contributes to tissue repair and organ homeostasis throughout adulthood. Inherited activating mutations in c-Met are associated with renal papillary carcinoma, and ligand-stimulated pathway activation has been implicated in the growth, neovascularization, invasiveness, and metastasis of several other human tumors. The restorative, as well as the deleterious potential of this pathway make it a promising target for therapeutic intervention against several degenerative and neoplastic diseases. The HGF gene encodes full-length HGF, and two truncated isoforms (NK1 and NK2) which consist of the N-terminal domain (N) linked to the first one (K1) or two (K1+K2) kringle domains. Both truncated isoforms are motogenic; NK1 also retains the mitogenic and morphogenic potency of HGF, while NK2 is a competitive antagonist of these activities. The primary heparin and receptor binding sites of HGF reside in the N and K1 domains, respectively. Three dimensional structures of N and NK1 obtained using NMR spectroscopy and X-ray crystallography suggest that ligand dimerization, augmented by heparin binding, may facilitate receptor activation. This information provides the basis for [1] determining the solution structure of an NK1-heparin complex; [2] locating K2 in NK2 to learn the structural basis for its antagonistic properties; [3] identifying receptor binding residues in K1, [4] creating NK1 and NK2 mutants with altered heparin and receptor binding properties, and [5] assessing these proteins as activators or inhibitors of HGF signaling using cultured cells and intact animals. Achieving these goals will help elucidate the mechanism by which HGF