Rockville, MD 20857, 301–827–7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss supplemental new drug application (NDA) 21–386, ZOMETA (zoledronic acid for injection), Novartis Pharmaceuticals Corp., indicated for the treatment of bone metastases in patients with multiple myeloma, breast cancer, prostate cancer and other solid tumors.

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 January 24, 2002. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 24, 2002, 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. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by January 24, 2002, to address issues specific to the topic before the committee.

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

Dated: December 10, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–31025 Filed 12–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0503]

Draft Compliance Policy Guide: ''Filth from Insects, Rodents, and Other Pests in Food;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) currently entitled ''Filth from Insects, Rodents, and Other Pests in Food.'' The purpose of this draft CPG is to revise, clarify, and redefine existing guidance on the interpretation of filth in foods within the context of current science. The draft CPG will provide written guidance to FDA components as well as to the industry.

DATES: Submit written or electronic comments on this draft CPG by February 19, 2002.

ADDRESSES: Submit written requests for single copies of the draft CPG ''Filth from Insects, Rodents, and Other Pests in Food'' to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or FAX your request to 301–827–0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written comments on the draft CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

Technical Questions Concerning Filth in Foods: Alan R. Olsen, Microanalytical Branch (HFS–315), Office of Plant, Dairy Foods, and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4438, FAX 202–205–4091.

Questions Concerning Regulatory Actions: MaryLynn Datoc, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0413, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed a draft CPG to revise, clarify, and redefine existing guidance on foods that contain filth from insects, rodents, and other pests to reflect recent advances in science. The purpose of this draft CPG is to provide clear policy to FDA's field and headquarters staff with regard to filth from insects, rodents, and other pests in foods. It also contains information that may be useful to the regulated industry and to the public.

The draft CPG, when finalized, will supersede the current CPG and represents the agency's current thinking on the subject. 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 an approach satisfies the requirements of applicable statutes or regulations.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft CPG entitled ''Filth from Insects, Rodents, and Other Pests in Food.'' Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft CPG and received comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the draft CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the draft CPG and may be accessed at http://www.fda.gov/ora under ''Compliance References.''

Dated: December 11, 2001.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–31024 Filed 12–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Neurotrophic Components of the ADNF I Complex

Brenneman et al. (NICHD)
DHHS Reference No. E–209–01/0 filed 12 Sep 2001
Licensing Contact: Jonathan Dixon; 301/496–7056 ext. 270; *dixonj@od.nih.gov*

Neuronal cell death has been associated with a variety of diseases and conditions, including Alzheimer's, AIDS-related dementia, Huntington's disease, and Parkinson's disease to name a few. Neuronal cell death has also been associated with developmental retardation and learning impairments that have lifelong effects on individuals diagnosed with these conditions.

This invention discloses new Activity Dependent Neurotrophic Factor I (ADNF I) complex polypeptides. Previously, Activity Dependent Neurotrophic Factor (ADNF) polypeptides have been shown to prevent neuronal cell death. ADNF polypeptides are secreted by astroglial cells in the presence of vasoactive intestinal peptide (VIP). These new ADNF I complex polypeptides are effective for reducing neuronal cell death, for reducing oxidative stress, for reducing condition(s) associated with fetal alcohol syndrome in a subject, for enhancing learning and memory, both pre- and post-natally, and for other conditions.

With these additional ADNF I complex polypeptides it will be easier to target specific receptors in different cell types and to individually tailor drug treatment regimes to those afflicted with neurodegenerative disorders.

Utilization of FPRL1 as a Functional Receptor by Serum Amyloid A (SAA)

Ji Ming Wang et al. (NCI)
DHHS Reference No. E–167–99/0 filed 22 Sep 1999 (PCT/US99/21770, WO 01/21188)
Licensing Contact: Marlene Shinn; 301/496–7056 ext. 285; *shinnm@od.nih.gov*

This technology identifies a means for modulating the interaction of Serum Amyloid A (SAA) with its functional receptor FPRL1. This modulation may have therapeutic applications in treating diseases such as infections, organ rejection, rheumatoid arthritis, atherosclerosis, neoplasms, and amyloidosis. The SAA, an acute phase protein, is normally present in serum but increases by 1,000 fold in systemic inflammatory conditions and is associated with leukocyte migration in these disease states. This technology identifies various means to modulate the association of SAA and FPRL1 in a SAA–FPRL1 complex or method of identifying agents that associate with the complex. It is available for immediate licensing and research collaborations via a Cooperative Research and Development Agreement (CRADA).

Dated: December 10, 2001.

Jack Spiegel,

Director, Division of Technology, Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 01–31048 Filed 12–17–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel NCCAM SEP ZAT1 K–02.

Date: January 4, 2002.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: 2 Democracy Plaza, 6707 Democracy Boulevard, Conference Room 701, Bethesda, MD 20892.

Contact Person: William A. Kachadorian, PhD., Scientific Review Administrator, Office of Scientific Review, National Center for Complementary and Alternative Medicine, 6707 Democracy Blvd, Ste 106, Bethesda, MD 20892–5475, (301) 594–2014, *kachadow@mail.nih.gov.*

Dated: December 10, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–31047 Filed 12–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIDCR Special Grants Review Committee, Review of R03, F32, K02, K08, K22, K23, K24 Grants.

Date: February 21–22, 2002.

Time: 8 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Yujing Liu, PHD, MD, Scientific Review Administrator, National Institute of Dental and Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN44F, Bethesda, MD 20892, (301) 594–2372.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: December 7, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–31043 Filed 12–17–01; 8:45 am]

BILLING CODE 4140–01–M