

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]

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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]

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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.