Targeted Primary Prevention and Early Intervention Projects

Paul DuCommun or William Somers, Division of Demonstration Programs (301) 443–0377

Mailing Address for the Above Individuals

Office for Substance Abuse Prevention, Alcohol, Drug Abuse, and Mental Health Administration, Room 9A–54, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Donald Ian Macdonald, M.D.,

Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 87–5519 Filed 3–13–87; 8:45 am]

BILLING CODE 4160–20–M

Food and Drug Administration

Advisory Committee; Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

Meeting: The following advisory committee meeting is announced:

General Hospital and Personal Use Devices Panel

Date, time, and place. April 6 and 7, 9 a.m., Rm. 503A, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC.

Type of meeting and contact person. Open public hearing, April 6, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 12 m.; closed presentation of data, 1 p.m. to 2 p.m.; closed committee deliberations, 2 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 4 p.m.; open public hearing, April 7, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 12 m.; closed presentation of data, 1 p.m. to 2 p.m.; closed committee deliberations, 2 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 4 p.m.; Andrea A. Wargo, Center for Devices and Radiological Health (HFZ–420), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7750.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 23, 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 required to make their comments.

Open committee discussion. The committee will discuss safety and effectiveness data for a closed loop infusion device and for an implantable infusion pump.

Closed presentation of data. Trade secret and/or confidential commercial information will be presented to the committee regarding materials, computer software, and manufacturing information for the closed loop infusion device; and materials, design, and manufacturing information for the implantable infusion pump. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Closed committee deliberations. The committee will discuss trade secret and/or confidential commercial information on materials, computer software, and manufacturing information regarding the closed loop infusion device; and materials, design, and manufacturing information regarding the implantable infusion pump. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (Subpart C of 21 CFR Part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR Part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be requested from the Dockets Management Branch (HFA–305), Rm. 4–62, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94–409), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of

personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA,s regulations (21 CFR Part 14) on advisory committees.

Dated: March 10, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 87-5524 Filed 3-13-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87F-0014]

General Electric Co.; Filing of Food Additive Petition

AGENCY: The Food and Drug Administration.

ACTION: Notice.

SUMMARY: Food and Drug Administration (FDA) is announcing that General Electric Co. has filed a petition proposing that the food additive regulations be amended to provide for a change of a specification for poly(tetramethylene terephthalate) copolymers used as articles or components of articles intended to contact food.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 7B3983) has been filed by General Electric Co., Plastics Group, Pittsfield, MA 01201, proposing that § 177.1660 *Poly (tetramethylene terephthalate)* (21 CFR 177.1660) be amended in paragraph (c)(1) to lower the inherent viscosity specification from the current 0.8 to 0.6.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: March 6, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-5521 Filed 3-13-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87F-0013]

Union Carbide Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Union Carbide Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of glutaraldehyde as a chemical for controlling microorganisms in cane-sugar and beet-sugar mills.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. Sw., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 7A3981) has been filed by Union Carbide Corp., P.O. Box 670, Bound Brook, NJ 08805, proposing that § 173.320 *Chemicals for controlling micro-organisms in cane-sugar and beet-sugar mills* (21 CFR 173.320) be amended to provide for the safe use of glutaraldehyde as a chemical for controlling microorganisms in cane-sugar and beet-sugar mills.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: March 6, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-5520 Filed 3-13-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87P-0017]

Canned Pacific Salmon Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to the Carnation Co. to market test canned skinless and boneless chunk salmon packed in water. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the food.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than June 15, 1987.

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFF-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0110.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to the Carnation Co., Los Angeles, CA 90036.

The permit covers limited interstate marketing tests of canned skinless and boneless chunk salmon packed in water. The test product deviates from the standard of identity for canned Pacific salmon (21 CFR 161.170) in three ways: (1) The form of pack is chunk, i.e., not less than 50 percent of the drained weight of the salmon is retained on a ½-inch mesh screen; (2) the skin and backbone, i.e., vertebrae and associated bones (neural spines and ventral ribs), are removed; and (3) water, in an amount not to exceed 10 percent of the water capacity of the can, will be used as a packing medium and to aid in dispersion of salt. The test product meets all requirements of § 161.170 with the exception of these deviations. The permit provides for the temporary marketing of 110,000 cases of test product containing twenty-four 6½-ounce cans each. The test product will be distributed throughout the United States.

The test product is to be manufactured at the Petersburg Fisheries plant located in Petersburg, AK 99833.

Each of the ingredients used in the food is stated on the label as required by the applicable sections of 21 CFR Part 101. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than June 15, 1987.

Dated: March 6, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-5523 Filed 3-13-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 83N-0009]

FD&C Blue No. 2; Availability of the Commissioner's Decision Following a Formal Evidentiary Public Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the Commissioner's decision on a petition seeking permanent listing of FD&C Blue No. 2 as a color additive for general use in food and ingested drugs. The Commissioner has determined that FD&C Blue No. 2 has been shown safe for such uses, thereby upholding the initial decision of the Administrative Law Judge granting permanent listing of the color additive pursuant to a final rule published in the **Federal Register** of February 4, 1983 (48 FR 5252), codified at 21 CFR 74.102. The Commissioner's decision largely adopts the initial decision of the Administrative Law Judge in finding that a statistically significant increased number of brain gliomas in male rats in a long-term feeding study of FD&C Blue No. 2 was not compound related. The Commissioner's decision concludes that the results of the rat study, a long-term feeding study in mice, and several short-term tests demonstrate the safety of FD&C Blue No. 2 to a reasonable certainty. The Commissioner's decision is available to the public on request.

ADDRESS: A copy of the decision is available for public examination at, and requests for single copies may be sent to, the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. (Send two self-addressed adhesive labels to assist the Branch in processing your requests.)

FOR FURTHER INFORMATION CONTACT: Paul D. Lepore, Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2390.

SUPPLEMENTARY INFORMATION: This notice is issued in accordance with 21 CFR 12.130(e).

Dated: March 6, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[Fr Doc. 87-5522 Filed 3-13-87; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Project Grants for Outpatient Medical Facility Improvement; Availability

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of grant availability.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications for outpatient medical facility improvement grants under the authority of section 1610(b) of the Public Health Service (PHS) Act (42 U.S.C. 300r(b) are being accepted. The grants will be available to private nonprofit entities which are already receiving support for either a migrant health center under section 329 of the Act or for a community health center under section 330 of the Act. Applicants should be advised that the Administration is requesting a rescission of the funding appropriated for this program. This notice regarding applications does not reflect any change in this policy. However, should the rescission not be approved by Congress, this solicitation of applications will assure that grants can be awarded in a timely fashion consistent with the needs of the programs and deteriorating physical plants can be upgraded as soon as possible to alleviate potentially hazardous fire and safety code violations.

DATE: Potential applicants should submit a letter of intent to apply for a section 1610(b) grant by the close of business March 26, 1987, to the Grants Management Officer Bureau of Resources Devolopment (BRD) at the address below. To receive consideration, applications for section 1610(b) outpatient medical facility improvement grants must be received by the close of business May 15, 1987, by the Grants Management Officer at the address below. Applications shall be considered as meeting the deadline date if they are either:

(1) Received on or before the deadline date, or

(2) Postmarked on or before the deadline and received in time for submission to the review committee. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be acceptable as proof of timely mailing.

FOR FURTHER INFORMATION CONTACT: Requests for technical and programmatic information should be directed to Mr. Gayle Dolecek, Office of Health Facilities Bureau of Resources Development, Room 11A-10, 5600 Fishers Lane Rockville, Maryland 20857, 301/443-0271. Requests for applications, completed application kits (SF 424, approved under OMB Clearance Number 0348-0006) and other information related to grants management should be directed to Mr. Donald C. Parks, Grants Management Officer, Bureau of Resources Development, Room 9-03, 5600 Fisher Lane, Rockville, Maryland 20857, 301/443-2630.

SUPPLEMENTARY INFORMATION: Section 1610(b) authorizes the Secretary of Health and Human Services to make grants to public and nonprofit entities for construction, renovation, expansion,