

participants, and an indication of the approximate time required to make their comments.

Closed committee deliberations. The committee will hear trade secret and/or confidential commercial information relevant to the investigational new drug (IND) application 30,045. 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.

Details on the agenda, questions to be addressed by the committee, and a current list of committee members are available from the contact person before and after the meeting. Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI-35), Food and Drug Administration, Rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

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: November 16, 1988.

James S. Benson,
Acting Deputy Commissioner.
[FR Doc. 88-27051 Filed 11-22-88; 8:45 am]
BILLING CODE 4160-01-M

[Docket No. 88F-0372]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ethylene oxide-propylene oxide block copolymer, polyethylene glycol (600) dioleate, propylene glycol monooleate and isopropyl alcohol as boiler water additives.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street

SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug and Cosmetic Act (section 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, has filed a petition (FAP 8A4111) proposing that 21 CFR Part 173—*Secondary Direct Food Additives Permitted in Food and Human Consumption* be amended to provide for the safe use of ethylene oxide-propylene oxide block copolymer, polyethylene glycol (600) dioleate, propylene glycol monooleate and isopropyl alcohol as boiler water additives.

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: November 14, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-27053 Filed 11-22-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88G-0371]

The NutraSweet Co.; Filing of Petition for Affirmation of Grasp Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that The NutraSweet Co., has filed a petition (GRASP 8G0345), proposing to affirm that microparticulated egg and milk protein product is generally recognized as safe (GRAS) as a direct human food ingredient.

DATE: Comments by January 23, 1989.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5), 72 Stat. 1786 (21

U.S.C. 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 8G0345) has been filed by The NutraSweet Co., 1751 Lake Cook Road, Deerfield, IL 60015, proposing that microparticulated egg and milk protein product be affirmed as GRAS for use as a direct human food ingredient.

The GRAS affirmation petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 and 170.35 (21 CFR 170.30 and 170.35) is filed by the agency. There is no pre-filing review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

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).

Interested persons may, on or before January 23, 1989, review the petition and/or file comments (two copies, identified with the docket number found in brackets in the heading of this document) with the Dockets Management Branch (address above). Comments should include any available information that would be helpful in determining whether this substance is, or is not, GRAS for the proposed use. A copy of the petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 14, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-27054 Filed 11-22-88; 8:45 am]

BILLING CODE 4160-01-M

Consumer Participation; Notice of Open Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following district consumer exchange meetings: DETROIT DISTRICT OFFICE, chaired by Louis F. Schneider, Acting District Director. The topics to be

discussed are tampon labeling and other items of current concern.

DATE: Tuesday, December 6, 1988, 10 a.m.

ADDRESS: George Potter Larrick Bldg., Conference Rm., 1560 East Jefferson Ave., Detroit, MI 48207.

FOR FURTHER INFORMATION CONTACT: Evelyn DeNike, Consumer Affairs Officer, Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207, 313-226-6260.

DETROIT DISTRICT OFFICE, chaired by Kenneth Ewing, Grand Rapids Resident Post Supervisory Investigator. The topic to be discussed are tampon labeling and other items of current concern.

DATE: Wednesday, December 7, 1988, 10 a.m.

ADDRESS: Kent County Public Health Facility, 700 Fuller Ave. NE., Grand Rapids, MI 49503.

FOR FURTHER INFORMATION CONTACT: Evelyn DeNike, Consumer Affairs Officer, Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207, 313-226-6260.

SUPPLEMENTARY INFORMATION:

The purpose of these meetings is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: November 18, 1988.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-27116 Filed 11-22-88; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Pub. L. 92-463, the Annual Report for the following Health Resources and Service Administration Federal Advisory Committee has been filed with the Library of Congress:

Maternal and Child Health Research Grants Review Committee

Copies are available to the public for inspection at the Library of Congress Newspaper and Current Periodical Reading Room, Room 1026, Thomas

Jefferson Building, Second Street and Independence Avenue SE., Washington, DC, or weekdays between 9:00 a.m. and 4:30 p.m. at the Department of Health and Human Services, Department Library, HHS North Building, Room G-400, 330 Independence Avenue SW., Washington, DC, telephone (202) 245-6791. Copies may be obtained from:

Gontran Lamberty, Dr. Ph.H., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Room 6-17, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-2190.

Date: November 17, 1988.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 88-27049 Filed 11-22-88; 8:45 am]

BILLING CODE 4160-15-M

Health Care Financing Administration

[IOA-018-N]

Medicare Program; Meeting of the Advisory Committee on Home Health Claims

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces a meeting of the Advisory Committee on Home Health Claims for the purpose of studying the reasons for the increase in the denial of claims for home health services during 1986 and 1987, the ramifications of the increase, and the need to reform the process involved in these denials. The meeting will be open to the public.

DATE: The meeting will be held on December 8, 1988 from 9:30 a.m. to 4:30 p.m., Mountain Standard Time (MST), and on December 9, 1988 from 9:30 a.m. to 2:00 p.m., MST.

ADDRESS: The meeting will be held in the La Posada de Albuquerque, 125 Second Street, NW., Albuquerque, New Mexico 87102.

FOR FURTHER INFORMATION, CONTACT: Wilhelm Pickens: (301) 966-7476.

SUPPLEMENTARY INFORMATION: On July 1, 1988, the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100-360) was enacted. Section 427 of Pub. L. 100-360 established the Advisory Committee on Medicare Home Health Claims. Additionally, section 427 requires the Advisory Committee to report by July 1, 1989 to the Administrator of the Health Care Financing Administration (HCFA) and to the Committees on Ways and Means and Energy and Commerce of the

House of Representatives, and the Committee on Finance of the Senate, its findings on the denial of claims for home health services in 1986 and 1987. The Advisory Committee must study—

(1) The reasons for the increase in the denial of claims for home health services during 1986 and 1987;

(2) The ramifications of that increase; and

(3) The need to reform the process involved in the denials.

The Advisory Committee will address fully these three specified duties before it takes up any other questions. The recommendations of the Advisory Committee are intended to be used only at the option of HCFA and Congress.

Agenda items for the meeting will include presentations from experts in the field of home health services, and discussions of directions and issues to be addressed at subsequent meetings.

Agenda items are subject to change as priorities dictate.

(Catalog of Federal Domestic Assistance Program No. 13,774; Medicare—Supplementary Medical Insurance)

Dated: November 16, 1988.

William L. Roper,

Administrator, Health Care Financing Administration.

[FR Doc. 88-27125 Filed 11-22-88; 8:45 am]

BILLING CODE 4120-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Administration

[Docket No. N-88-1896]

Submission of Proposed Information Collections to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notices.

SUMMARY: The proposed information collection requirements described below have been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposals.

ADDRESS: Interested persons are invited to submit comments regarding these proposals. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management Officer, Department of Housing and

Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 755-6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total numbers of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: November 16, 1988.

John T. Murphy,

Director, Information Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Request of Occupied Conveyance (Handbook 4310.5 REV. 1)

Office: Housing

Description of the Need for the Information and Its Proposed Use:

This information collection is used by the occupant to request from HUD permission to remain as a tenant of a property that has been conveyed to HUD. HUD uses the information to determine if the occupant is financially able to pay the fair market rent.

Form Number: HUD-9539

Respondents: Individuals or Households and Businesses or Other For-Profit

Frequency of Submission: On Occasion
Reporting Burden: