DATES: Written comments on the petitioner's environmental assessment by September 18, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Diane E. Robertson, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 5B4471) has been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188. The petition proposes that the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) be amended to provide for the safe use of 2,2′-(2,5-thiophenediyl)-bis(5-*tert*-butylbenzoxazole) in all polymers intended for use in food packaging and in adhesives complying with § 175.105 *Adhesives* (21 CFR 175.105) and § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125).

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4 (b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before September 18, 1995, submit to the Dockets Management Branch (address above) written comments. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, 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: August 7, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–20567 Filed 8–17–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95G–0208]

Solvay Enzymes, Inc.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Solvay Enzymes, Inc., has filed a petition (GRASP 5G0415), proposing that pullulanase enzyme preparation derived from *Bacillus licheniformis* containing the pullulanase gene from *B. deramificans* be affirmed as generally recognized as safe (GRAS) for use as a direct human food ingredient.

DATES: Written comments by November 1, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Dennis M. Keefe, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3102.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Solvay Enzymes, Inc., P.O. Box 4226, Elkhart, IN 46514–0226, has filed a petition (GRASP 5G0415) proposing that a pullulanase enzyme preparation derived from *B. licheniformis* containing the pullulanase gene from *B. deramificans* be affirmed as GRAS for use in food as a direct human food ingredient.

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

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the agency. There is no prefiling 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 November 1, 1995, review the petition and/or file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–20566 Filed 8–17–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

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 meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates,

can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. September 8, 1995, 8 a.m., Corporate Bldg., rm. 20B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Marriott Washingtonian Hotel, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301–590–0044 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Closed committee deliberations, 8 a.m. to 9 a.m.; open public hearing, 9 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 4:30 p.m.; Michael Bazaral, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, or the FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anesthesiology and Respiratory Therapy Devices Panel, code 12624.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational 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 August 29, 1995, 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 hear presentations and discuss a draft guidance document for data to support premarket notification submissions for ventilators, including both conventional positive pressure ventilators and positive pressure ventilators which function using a continually open exhalation port associated with the patient mask or other patient connection.

Single copies of the draft guidance document are available from the contact person for this meeting. Copies may also be obtained through the Division of Small Manufacturer's Assistance; requests should reference document 500. For delivery by mail, fax requests to Les Grams at 301–443–8818 (include mailing address). Copies are available from Facts on Demand (1–800–899–0311) and are available from the Electronic Docket via terminal or personal computer (1–800–252–1366); to receive detailed instructions for requesting electronic transmission (including fax), fax a request for !BP__DSMA.FAX to Geoffrey Clark at 301–443–8818.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. 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.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing 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. 1–23, 12420 Parklawn Dr., 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 may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner 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) (5 U.S.C. app. 2, 10(d)), 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, deliberation 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 (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: August 10, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–20460 Filed 8–17–95; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Availability of Funds for Grants to Provide Health Care for Individuals With Hansen's Disease

AGENCY: Health Resources and Services Administration.

ACTION: Notice of available funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that it anticipates approximately $2.0 million will be available in fiscal year (FY) 1996, based on the President's budget, for awards under section 320 of the Public Health Service (PHS) Act to provide outpatient medical care and treatment for individuals with Hansen's Disease.

This program announcement is subject to the appropriation of funds. Applicants are advised that this application announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The Hansen's Disease Program is related to the priority areas for health promotion and disease prevention services. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report: Stock No.017–001–00474–0) or *Healthy People 2000* (Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9323 (Telephone (202) 783–3238).

PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

DUE DATE: Applications are due by October 16, 1995. Applications will be considered as having met the deadline if they are: (1) Received on or before the established deadline date; or (2) postmarked on or before the deadline date and received in time for orderly processing. Applicants must obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service in lieu of a postmark. Private metered postmarks are not acceptable as proof of timely mailing. Late applications will be returned to the sender.

ADDRESSES: Application kits (Form PHS 5161–1 with revised face sheet DHHS form 424, as approved by the OMB under control number 0937–0189) may be obtained from, and completed applications sent to: Bureau of Primary Health Care, c/o Houston Associates, Inc., 1010 Wayne Avenue, Suite 1200, Silver Spring, Maryland 20910. The telephone number is (800) 523–2192. The Fax number is (800) 523–2193.

FOR FURTHER INFORMATION CONTACT: Information or technical assistance regarding business management issues should be directed to Pam Hilton, Office of Grants Management, Bureau of Primary Health Care, 4350 East-West Highway, Bethesda, Maryland 20814. The telephone number is (301) 594–4255. The Fax number is (301) 594–4073. Her internet address is: philton@hrsa.ssw.dhhs.gov.

Technical and/or programmatic information should be directed to Irma E. Guerra, Ambulatory Care Program, Gillis W. Long Hansen's Disease Center, 5445 Point Clair Road, Carville, Louisiana 70721. The telephone number is (800) 642–2477.

SUPPLEMENTARY INFORMATION: Hansen's Disease (HD) affects the skin, peripheral nerves, anterior part of the eyes, and the nasal area. Patients are in the age range of 20–77, have a male to female ratio of 2:1, and consist primarily of Hispanic and Asian populations. The Division of National Hansen's Disease Programs (DNHDP) provides outpatient HD medical care and services to patients in the United States (U.S.) and Puerto Rico through the Ambulatory Care Program at the Gillis W. Long Hansen's Disease Center in Carville, Louisiana. Currently and historically, services have been offered in California, Florida, Illinois, Massachusetts, New York, Puerto Rico, Texas, and the State of Washington.

Patients are admitted to the Gillis W. Long Hansen's Disease Center only as authorized by medical staff at the Center.

Grants will range from $25,000 to $400,000 depending on the number of HD patients to be served by each entity. No more than 10 grants to entities serving 100 or more HD patients at $100,000 to $400,000 and no more than 4 grants to entities serving 50–100 HD