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

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


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 be amended to provide for the safe use of 2,2′-(2,5-thiophenediyl)-bis(5-tert-butylbenzoazoloxole) 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. 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).


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.

ADDRESS: Submit written comments to the Dockets Management Branch (HFS-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, 202-119-3809.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 201(s) and 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that pullulanase enzyme preparation derived from B. licheniformis containing the pullulanase gene from B. deramificans is recognized as safe (GRAS) for use as a direct human food ingredient.

DATES: Written comments by November 1, 1995.

ADDRESS: Submit written comments to the Dockets Management Branch (HFS-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, 202-119-3809.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 201(s) and 409(b)(5) (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 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.


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,