

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 The Flax Council of Canada, 465-167 Lombard Ave., Winnipeg, MB R3B 0T6, Canada, has filed a petition (GRASP 5G0416) proposing to affirm that low linolenic acid flaxseed oil is GRAS for use as a food oil. The petitioner proposes that solin oil be the common or usual name for low linolenic acid flaxseed oil.

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 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 June 10, 1996, review the petition and 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: March 13, 1996.
Eugene C. Coleman,
Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-7312 Filed 3-26-96; 8:45 am]
BILLING CODE 4160-01-F

[Docket No. 92G-0085]

Michael Foods, Inc.; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 2G0387) proposing that the use of β-cyclodextrin as a processing aid in reducing the cholesterol content of liquid eggs be affirmed as generally recognized as safe (GRAS).

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3071.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of March 30, 1992 (57 FR 10767), FDA announced that a petition (GRASP 2G0387) had been filed by Michael Foods, Inc., 324 Park National Bank Bldg., 5353 Wayzata Blvd., Minneapolis, MN 55416. This petition proposed that the use of β-cyclodextrin as a processing aid in reducing the cholesterol content of liquid eggs be affirmed as GRAS.

Michael Foods, Inc. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 7, 1996.
Alan M. Rulis,
Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.
[FR Doc. 96-7310 Filed 3-26-96; 8:45 am]
BILLING CODE 4160-01-F

[Docket No. 96N-0095]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of 49 New Drug Applications, 9 Abbreviated Antibiotic Applications, and 36 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 49 new drug applications (NDA's), 9 abbreviated antibiotic applications (AADA's), and 36 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: April 26, 1996.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1038.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

Application no.	Drug	Applicant
NDA 3-718	Synkayvite Tablets and Injection	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110.
NDA 3-977	Theelin	Parke-Davis, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 6-071	Berocca Injectable	Hoffman La Roche, Inc.
NDA 6-128	Sopronol Ointment	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 6-129	Sopronol Solution	Do.
NDA 6-130	Sopronol Powder	Do.
NDA 9-102	Antepar Tablets and Syrup	Burroughs Wellcome Co., 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709-2700.