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 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 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.

Application no.	Drug	Applicant
NDA 9–495	Marezine Injection	Do.
NDA 9–519	Doriden Tablets	Rhone-Poulenc Rorer Pharmaceuticals, Inc., 500 Arcola Rd., Colegeville, PA 19426–0107.
NDA 9–660	Noludar Tablets	Hoffman-La Roche, Inc.
NDA 10–209	Meti-Derm Cream	Schering Corp., 2000 Galloping Hill Rd., Kenilworth NJ 07033.
NDA 10–773	Correctol Tablets	Schering-Plough HealthCare Products, 110 Allen Rd., P.O. Box 276, Liberty Corner, NJ 07938–0276.
NDA 10–878	Visine Eye Drops	Pfizer Pharmaceuticals, 235 East 42d St., New York, NY 10017.
NDA 11–160	Thorexin Cough Medicine	The Purdue Frederick Co., 100 Connecticut Ave., Norwalk, CT 06856.
NDA 11–296	Sunbath Protective Tanning Cream	Revlon, Research Center, Inc., 121 Route 27, Edison, NJ 08818.
NDA 11–297	Sunbath Protective Tanning Lotion	Do.
NDA 11–657	Betaprone	Forest Pharmaceuticals, Inc., 909 Third Ave., New York NY 10022–4731.
NDA 11–844	Arthropan Liquid	The Purdue Frederick Co.
NDA 13–077	Xylocaine Suppositories	Astra Pharmaceutical Products, Inc., 50 Otis St., Westborough, MA 01581.
NDA 13–094	Clysodrast Evacuant Enema	Rhone-Poulenc Rorer Pharmaceuticals, Inc.
NDA 13–319	Iothalamate Sodium 80%	Mallinckrodt Medical Inc., 675 McDonnell Blvd., P.O. Box 5840, St. Louis, MO 63134.
NDA 13–638	Indoklon	OHMEDA, Inc., 110 Allen Rd., P.O. Box 804, Liberty Corner, NJ 07938.
NDA 14–359	Meprobamate Tablets	Halsey Drug Co., Inc., 245 Old Hook Rd., Westwood, NJ 07675.
NDA 14–740	Menrium Tablets	Hoffmann-La Roche, Inc.
NDA 16–144	Ethamide Tablets	Allergan, 2525 Dupont Dr., P.O. Box 19534, Irvin, CA 92713–9534.
NDA 16–219	Lemon Spree Deodorant Soap	Colgate-Palmolive Co., 909 River Rd., P.O. Box 1343, Piscataway, NJ 08855–1343.
NDA 16–264	Palmolive Gold Antibacterial Deodorant Soap	Do.
NDA 16–278	Tackle Medicated Soap	Do.
NDA 16–486	Antibacterial Deodorant Soap	Do.
NDA 16–768	Estrovus Tablets	Parke-Davis.
NDA 16–942	Halotex 1% Cream	Westwood-Squibb Pharmaceuticals, 100 Forest Ave., Buffalo, NY 14213–1091.
NDA 17–129	Cholebrine	Mallinckrodt Medical, Inc.
NDA 17–486	Heparin Injection	Akorn, Inc., P.O. Box 1220, Decatur, IL 62525.
NDA 18–144	Centrax Capsules	Parke-Davis
NDA 18–203	Liposyn 10%	Abbott Laboratories, D–389, Bldg. AP30, 200 Abbott Park Rd., Abbott Park, IL 60064–3537.
NDA 18–223	Multivitamin Additive for Injection	Do.
NDA 18–288	Hypnomidate Injection	Janssen Research Foundation, 1125 Trenton-Harbourton Rd., P.O. Box 200, Titusville, NJ 08560.
NDA 18–440	M.V.C. 9 + 3	Fujusawa USA, Inc., Parkway North Center, Three Parkway North, Deerfield, IL 60015–2548.
NDA 18–550	Rimadyl Tablets	Hoffmann-La Roche Inc.
NDA 18–555	Yutopar Tablets	Astra USA, Inc., P.O. Box 4500, Westborough, MA 01581–4500.
NDA 18–614	Liposyn 20%	Abbott Laboratories.
NDA 18–962	Manganese Chloride Injection	Do.
NDA 19–185	Oxytocin in 5% Dextrose Injection	Do.
NDA 19–228	Magnesium Sulfate Injection	Fujisawa USA, Inc.
NDA 19–271	Chromic Chloride Injection	Do.
NDA 19–786	Lopressor OROS	Ciba-Geigy Corp., 556 Morris Ave., Summit NJ 07901–1398.
NDA 50–502	Siseptin Injection	Schering Corp.
NDA 50–523	Vira-A	Parke-Davis.
NDA 50–532	Ilotycin Topical Solution	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis IN 46285.
AADA 60–842	Penicillin V. Potassium	Novo Nordisk Pharmaceuticals, Inc., 100 Overlook Center, suite 200, Princeton, NJ 08540–7810.
AADA 61–864	Cephradine	Apothecon Inc., P.O. Box 4500, Princeton, NJ 08543–4500.
AADA 61–976	Cephradine	Do.
AADA 62–047	Erythromycin Ethylsuccinate Oral Suspension	KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144–2555.
AADA 62–171	Chloramphenicol Ophthalmic Solution	Optopics Laboratories Corp., 32 Main St., P.O. Box 210, Fairton, NJ 08320–0210.

Application no.	Drug	Applicant
AADA 62–413	Gentamicin Sulfate in 9% Sodium Chloride	Abbott Laboratories.
AADA 62–586	Erythromycin Lactobionate for Injection	Do.
AADA 62–871	Cephalexin Capsules	Yoshitomi Pharmaceutical Industries, c/o Warner Chilcott Laboratories, 182 Tabor Rd., Morris Plains, NJ 07950.
AADA 62–872	Cephalex Capsules	Do.
ANDA 70–118	Diphenhydramine Hydrochloride Cough Syrup	Morton Grove Pharmaceutical, Inc., 6451 West Main St., Morton Grove, IL 60053.
ANDA 70–770	Dexbrompheniramine Maleate and Pseudoephedrine Sulfate Extended-Release Tablets.	Geneva Pharmaceuticals, Inc., 2555 West Midway Blvd., Broomfield, CO 80020.
ANDA 71–368	Propranolol Hydrochloride Tablets	Interpharm, Inc., Three Fairchild Ave., Plainview, NY 11803.
ANDA 71–369	Propranolol Hydrochloride Tablets	Do.
ANDA 71–370	Propranolol Hydrochloride Tablets	Do.
ANDA 71–371	Propranolol Hydrochloride Tablets	Do.
ANDA 71–819	Methylodpa and Hydrochlorothiazide Tablets	Novopharm, Ltd., c/o Granutec, Inc., 4409 Airport Dr. NW., Wilson, NC 27896.
ANDA 71–820	Methyldopa and Hydrochlorothiazide Tablets	Do.
ANDA 71–821	Methyldopa and Hydrochlorothiazide Tablets	Do.
ANDA 71–822	Mehyldopa and Hydrochlorothiazide Tablets	Do.
ANDA 74–106	Naproxen Sodium Tablets	Hamilton Pharmaceuticals, Ltd., c/o Syntex, Inc., 3401 Hillview Ave., P.O. Box 10850, Palo Alto, CA 94303.
ANDA 74–110	Naproxen Tablets	Do.
ANDA 80–059	Aminosalicylate and Aminosalicylic Acid Tablets, 846 milligrams (mg)/112 mg.	Wallace Laboratories, 301B College Road East, Princeton, NJ 08540.
ANDA 80–271	Methyltestosterone Sublingual Tablets	Rosemont Pharmaceutical Corp., 301 South Cherokee St., Denver, CO 80223.
ANDA 80–384	Procaine Hydrochloride Injection	Fujisawa USA, Inc.
ANDA 83–376	Esterified Estrogens Tablets	Hoffmann-La Roche, Inc.
ANDA 84–215	Esterified Estrogens Tablets	Do.
ANDA 84–216	Esterified Estrogens Tablets	Do.
ANDA 84–290	Potassium Chloride for Injection Concentrate	Fujisawa USA, Inc.
ANDA 85–266	Diphenoxylate Hydrochloride and Atropine Sulfate Tablets.	MD Pharmaceuticals, Inc., 3130 South Harbor Blvd., suite 320, Santa Ana, CA 92704.
ANDA 85–303	Amithriptyline Hydrochloride Tablets	Roche Products, Inc., State Road 670, Km. 2.7, P.O. Box 452, Manati PR 00674–0452.
ANDA 86–587	Phenobarbital with Belladonna Alkaloids Elixir	Halsey Drug Co., Inc.
ANDA 87–723	Diatrizoate Meglumine and Diatrizoate Sodium Injection.	Berlex Laboratories, Inc., 300 Fairfield Rd., Wayne NJ 07470–7358.
ANDA 87–724	Diatrizoate Meglumine and Diatrizoate Sodium Injection.	Do.
ANDA 87–725	Diatrizoate Sodium Injection	Do.
ANDA 87–726	Diatrizoate Meglumine Injection	Do.
ANDA 87–728	Diatrizoate Meglumine and Diatrizoate Sodium Solution.	Do.
ANDA 87–729	Diatrizoate Meglumine Injection	Do.
ANDA 87–731	Diatrizoate Meglumine Injection	Do.
ANDA 87–739	Diatrizoate Meglumine Injection	Do.
ANDA 87–768	Ipodate Sodium Capsules	Do.
ANDA 87–787	Potassium Chloride for Injection Concentrate	Fujisawa USA, Inc.
ANDA 88–739	Promethazine Hydrochloride and Codeine Phosphate Syrup.	Halsey Drug Co., Inc.
ANDA 88–868	Promethazine and Phenylephrine Hydrochlorides Syrup.	Do.
ANDA 88–870	Promethazine and Phenylephrine Hydrochlorides and Codeine Phosphate Syrup.	Do.
ANDA 88–913	Promethazine Hydrochloride and Dextromethorphan Hydrobromide Syrup.	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective April 26, 1996.

Dated: March 7, 1996.

Janet Woodcock,

Center for Drug Evaluation and Research.

[FR Doc. 96–7309 Filed 3–26–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Proposed Collection of Public Comment; Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the