ANNUAL BURDEN ESTIMATES

Instruments	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
14 Month Parent Interview, Child Assessment Protocol and Video-taping Protocol	3,230	1	2.5	8,075
Parent Services Follow-Up Interview—HSFIS	3,400	1	1.2	4,080
Parent Services Follow-Up Interview—Primary Caregiver	3,298	1	.83	2,737
Child Care Provider Interview—Child Care Centers	478	1	.25	120
Child Care Provider Interview—Family Day Care & Relative Providers	1,022	1	.5	511
Child Care Observation Protocol	1,261	1	2	2,522
Staff Questionnaire	170	1	.5	85

Estimated Total Annual Burden Hours: 18,130 hours.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: July 30, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 96–19809 Filed 8–2–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 84G–0257]

Enzyme Technical Association; Filing of Petition for Affirmation of GRAS Status; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a petition (GRASP 3G0016) filed by the Enzyme Technical Association (formerly the Ad Hoc Enzyme Technical Committee). The document proposed to affirm that certain enzyme preparations from animal, plant, and microbial sources are generally recognized as safe (GRAS) as direct human food ingredients. This amendment proposes to affirm that carbohydrase and protease enzyme preparations from *Bacillus amyloliquefaciens* are GRAS as direct human food ingredients.

DATES: Comments by October 21, 1996.

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

FOR FURTHER INFORMATION CONTACT: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3101.

SUPPLEMENTARY INFORMATION: In accordance with the procedures described in § 170.35 (21 CFR 170.35), the Ad Hoc Enzyme Technical Committee (now the Enzyme Technical Association), c/o Miles Laboratories, Inc., 1127 Myrtle St., Elkhart, IN 46514, submitted a petition (GRASP 3G0016) requesting that the following enzyme preparations be affirmed as GRAS for use in food:

1. Animal-derived enzyme preparations: Catalase (bovine liver); lipase, animal; pepsin; rennet; rennet, bovine; and trypsin.

2. Plant-derived enzyme preparations: Bromelain; malt; and papain.

3. Microbially-derived enzyme preparations: *Aspergillus niger*, var. (lipase, catalase, glucose oxidase, and carbohydrase); *B. subtilis*, var. (carbohydrase and protease mixtures); *Rhizopus oryzae* (carbohydrase); and *Saccharomyces* species (carbohydrase).

In the Federal Register of April 12, 1973 (38 FR 9256), FDA published a notice of filing of this petition and gave interested persons an opportunity to submit comments to the Dockets Management Branch (address above). The petition was amended by notices published in the Federal Register of: (1) June 12, 1973 (38 FR 15471), proposing affirmation that microbially derived enzyme preparations (carbohydrase, lipase, and protease) from *A. oryzae* are GRAS for use in food; (2) August 29, 1984 (49 FR 34305), proposing affirmation that the enzyme preparations ficin, obtained from species of the genus *Ficus* (fig tree), and pancreatin, obtained from bovine and porcine pancreas, are GRAS for use in food; and (3) June 23, 1987 (52 FR 23607), proposing affirmation that the enzyme preparation protease from *A. niger* is GRAS for use in food. In the June 23, 1987, notice, FDA also noted the petitioner's assertion that pectinase enzyme preparation from *A. niger* and lactase enzyme preparation from *A. niger* are included under carbohydrase enzyme preparation from *A. niger*, and that invertase enzyme preparation from *Saccharomyces cerevisiae* and lactase enzyme preparation from *Kluyveromyces marxianus* are both included under carbohydrase enzyme preparation from species of the genus *Saccharomyces*. The agency further noted that, therefore, pectinase enzyme preparation from *A. niger*, lactase enzyme preparation from *A. niger*, invertase enzyme preparation from *S. cerevisiae*, and lactase enzyme preparation from *K. marxianus* were to be considered part of the petition. Interested persons were given an opportunity to submit comments to the Dockets Management Branch (address above) on each amendment.

Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), and the regulations for affirmation of GRAS status in § 170.35, notice is given that the Enzyme Technical Association has submitted a further amendment to its petition (GRASP 3G0016). The amendment proposes that carbohydrase and protease enzyme preparations from *B. amyloliquefaciens* be affirmed as GRAS for use as direct human food ingredients based on the taxonomic separation of *B. subtilis* and *B. amyloliquefaciens* in

1987. The amendment has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in 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 agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before October 21, 1996, review the amendment 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 2, 1996.

Alan M. Rulis,

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

[FR Doc. 96–19743 Filed 8–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0257]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of 87 New Drug Applications, 18 Abbreviated Antibiotic Drug Applications, and 103 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 87 new drug applications (NDA's), 18 abbreviated antibiotic applications (AADA's), and 103 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: September 4, 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 6–54	Progstigmin (neostigmine bromide solution) Opthalmic Solution, 5%.	Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 5–319	Pantopaque (iophendylate) Injection	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134–2099.
NDA 6–135	Folic Acid	Lilly Research Laboratories, Lilly Corporate Center, Indianopolis, IN 46285.
NDA 6–213	Propylthiouracil Tablets	Do.
NDA 6–215	Delphicol Tablets and Solution	Lederle Laboratories, Pearle River, NY 10965.
NDA 6–333	Synophylate (theophylline sodium glycinate) Elixir	Central Pharmaceuticals, Inc., 120 East Third St., Seymour, IN 47274.
NDA 6–386	Mol-Iron Liquid	Schering-Plough Corp., 110 Allen Rd., P.O. Box 276, Liberty Corner, NJ 07938–0276.
NDA 6–686	Dramamine Liquid	Richardson-Vicks, Inc., One Far Mill Crossing, Shelton, CT 06484.
NDA 6–911	Sulfisoxazole Syrup/Pediatric Suspension	Roche Pharmaceuticals, 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 8–082	Propion Gel	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101–8299.
NDA 8–855	Milontin 500 milligram (mg) Kapseals	Parke-Davis Pharmaceutical Research, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 8–951	Pagitane HCl Tablets	Lilly Research Laboratories.
NDA 9–008	Salpix Contrast Medium	The R. W. Johnson Pharmaceutical Research Institute, Rt. 202, Box 300, Raritan, NJ 08869–0602.
NDA 9–115	Serpasil Tablets and Elixir	Ciba-Geigy Corp., 556 Morris Ave., Summit, NJ 07901.
NDA 9–220	Di-Isopacin	Consolidated Midland Corp., 16–20 Main St., Brewster, NY 10509.
NDA 9–268	Choledyl Tablets, Pediatric Syrup, and Elixir,	Parke-Davis Pharmaceutical Research.
NDA 9–296	Serpasil Apresoline	Ciba-Geigy Corp.
NDA 9–309	Dionosil Oily	Glaxo, Inc., Five Moore Dr., P.O. Box 13358, Research Triangle Park, NC 27709.
NDA 9–434	Serpasil Parenteral Solution	Ciba-Geigy Corp.
NDA 9–750	Valmid Capsules, 500 mg	Lilly Research Laboratories.
NDA 10–291	Cortril Soluble Parenteral	Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755.
NDA 10–599	Tral Filmtab	Pharmaceutical Products Division, Abbott Laboratories, One Abbott Park Rd., Abbott Park, IL 60064–3500.
NDA 10–670	ORINASE Tablets	The Upjohn Co., 700 Portage Rd., Kalamazoo, MI 49001–0199.
NDA 10–710	Toleron Tablets and Suspension	Wallace Laboratories, Cranbury, NJ 08512.
NDA 10–776	DELTA-CORTEF Eye Drops, S.S.	The Upjohn Co.
NDA 10–911	BUCLADIN-S Tablets	Zeneca, 1800 Concord Pike, Wilmington, DE 19897.