FDC date	State	City	Airport	FDC No.	SIAP
02/14/96	NE	Falls City	Brenner Field	FDC 6/1017	NDB OR GPS–A, AMDT 3. . .
02/14/96	TX	Fort Worth	Fort Worth Meacham Intl	FDC 6/1023	LOC BC RWY 34R, AMDT 7. . .
02/15/96	CA	Lakeport	Lampson Field	FDC 6/1036	NDB OR GPS–A ORIG–A. . .
02/20/96	CA	Victorville	Southern California Intl	FDC 6/1111	ILS RWY 17 ORIG. . .

FR Doc. 96–4688 Filed 2–28–96; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 83G–0062]

Direct Food Substances Affirmed as Generally Recognized as Safe; Lactase Enzyme Preparation From Candida Pseudotropicalis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that lactase enzyme preparation derived from *Candida pseudotropicalis* for use in milk and milk-derived products to hydrolyze lactose is generally recognized as safe (GRAS). This action is in response to a petition submitted by Pfizer, Inc.

DATES: Effective February 29, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications listed in new § 184.1387, effective February 29, 1996.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3097.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), Pfizer, Inc., 235 East 42d St., New York, NY 10017, submitted a petition (GRASP 2G0282) proposing that lactase enzyme preparation from *C. pseudotropicalis* be affirmed as GRAS for use as a direct human food ingredient. (Lactase, the enzyme, is to be distinguished from lactase enzyme preparation, which contains lactase as the principal active component but also contains other components derived from the production organism and fermentation media. This document will refer to the former as ''lactase'' and to the latter as ''lactase enzyme preparation.'') Lactase enzyme preparation is used to hydrolyze lactose in milk and milk products.

FDA published a notice of filing of this petition in the Federal Register of March 29, 1983 (48 FR 13098), and gave interested persons an opportunity to submit comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. FDA received no comments in response to that notice.

II. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances added to food. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food (§ 170.30(a)). General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive, and ordinarily is to be based upon generally available data and information concerning the pre-1958 history of use of the food ingredient (§ 170.30(c)).

The petition states that *C. pseudotropicalis* was isolated from dairy products prior to 1958 (Refs. 1 and 2). Therefore, the petition argues, lactase produced by the organism has been part of the human diet for many years and may be presumed to have been in common use in food prior to January 1, 1958. The petition also states that Pfizer, Inc., first began commercial production of lactase enzyme preparation derived from *C. pseudotropicalis* in 1982 for use in certain dairy products.

The agency recognizes that *C. pseudotropicalis* was isolated from dairy products prior to 1958. However, lactase enzyme preparation derived from *C. pseudotropicalis* does not itself have a history of common use as an ingredient in food before 1958. Therefore, the enzyme preparation does not qualify for GRAS status based on a history of common use in food (§ 170.30(c)). Accordingly, FDA has evaluated the enzyme preparation on the basis of scientific procedures under § 170.30(b).

In evaluating this petition, the agency reviewed information concerning: (1) The identity and function of the enzyme, (2) the production and purification of the lactase enzyme preparation, and (3) the safety of the production organism and the finished lactase enzyme preparation.

III. Identity and Technical Effect

Lactase is the accepted name for the enzyme β-D-galactoside galactohydrolase (EC 3.2.1.23), which catalyzes the hydrolysis of the disaccharide lactose to its component monosaccharides, glucose and galactose. Lactase enzyme preparations may be produced by fermentation utilizing any of a large number of microorganisms. A typical example is the enzyme produced by the yeast *Kluyveromyces lactis* (Ref. 3).

The lactase preparation that is the subject of this petition is a soluble enzyme preparation derived from the yeast *C. pseudotropicalis* and is composed of the enzyme lactase as the principal active ingredient, other components derived from the production organism and the fermentation media, residual amounts of processing aids, and substances added as stabilizers or diluents. The petitioned enzyme preparation meets the general and additional requirements for enzyme preparations found in the Food Chemicals Codex, 3d ed. (1981), which are incorporated by reference in § 184.1387 (Ref. 4).

Lactase enzyme preparation is intended for use in hydrolyzing lactose to reduce the lactose content of food products. The petitioner provided published information to demonstrate that lactase enzyme preparation from *C. pseudotropicalis* hydrolyzes lactose in milk and milk products.

IV. Production and Purification of Lactase Enzyme Preparation

The lactase enzyme preparation that is the subject of this petition is produced by controlled aerobic fermentation using a pure culture of the food-derived yeast *C. pseudotropicalis*, aseptically grown in a medium containing suitable food-grade carbohydrates, proteins, mineral salts, and processing aids. The isolated cells are mixed with a warm buffer solution consisting of potassium phosphate (mono- and dibasic) and manganous sulfate and allowed to autolyze for up to 24 hours. The resulting material is clarified to remove cell debris and other insoluble solids, and the lactase-containing yeast extract is concentrated by processes appropriate for food use, including ultrafiltration. Glycerol and/or sorbitol may be added as stabilizers, and suitable preservatives may be incorporated during processing. The stabilized lactase preparation is adjusted to a standard potency using a combination of water mixed with glycerol or sorbitol.

V. Safety Information

In its petition, Pfizer, Inc., provided published information to document that the organism *C. pseudotropicalis* was isolated from dairy products as early as 1952 (Refs. 1 and 2). Pfizer, Inc., argues that since the organism is a copious producer of lactase (Ref. 5), both the organism and the lactase it produces have been ingested by man for many years. In addition, Pfizer, Inc., points out that *C. pseudotropicalis* resembles *K. fragilis* (a yeast, also known as *Saccharomyces fragilis*, that is approved as a direct food additive ((§ 172.896) (21 CFR 172.896))) in all respects except that *C. pseudotropicalis* is unable to reproduce sexually (Refs. 1 and 6). *K. fragilis*, like *C. pseudotropicalis*, has been isolated from dairy products (Refs. 1 and 7); in fact, the organisms are often found together in dairy foods (Ref. 5).

Pfizer, Inc., presented published reports to establish the similarity between *C. pseudotropicalis* and *K. fragilis*. For example, in an electrophoretic comparison of enzymes, a method used to clarify the taxonomical and physiological relationships among strains, the enzymatic patterns of *C. pseudotropicalis* and its perfect state, *K. fragilis*, were shown to coincide (Ref. 8). Further, a study using a deoxyribonucleic acid (DNA) reassociation technique showed that, within the accuracy permitted by the technique, *C. pseudotropicalis* and *K. fragilis* have identical DNA sequences (Ref. 9).

The close similarity between the source microorganism (*C. pseudotropicalis*) and *K. fragilis*, which FDA has determined is safe for use as a direct food additive (§ 172.896), supports the safety of the enzyme preparation (Refs. 10 and 11). Further, the information submitted by the petitioner establishes that lactase produced by both yeasts has been ingested by humans for many years with no reported adverse effects (Ref. 12).

To further document the safety of *C. pseudotropicalis*, Pfizer, Inc., presented a published study which compared the pathogenic potential of several industrial yeasts with that of established pathogens. The study found that neither *C. pseudotropicalis* nor *K. fragilis* produced signs of tissue invasion or disease. The authors of the study categorized both organisms in a group of nonpathogenic organisms (Ref. 13). Finally, Pfizer, Inc., submitted unpublished corroborative studies conducted in mice to confirm the nonpathogenicity of *C. pseudotropicalis*.

After conducting a review of the literature and evaluating these studies, the agency concludes that *C. pseudotropicalis* is neither pathogenic nor toxicogenic (Refs. 14 and 15). Furthermore, the agency has determined that the autolysis and filtration steps used in producing and purifying the lactase enzyme preparation effectively remove viable cells of the production organism (Ref. 15).

Pfizer, Inc., also presented corroborative unpublished toxicity studies to establish the safety of lactase enzyme preparation derived from *C. pseudotropicalis*. These were: (1) An acute oral toxicity study in rats, (2) mutagenic and cytogenetic assays, and (3) 90-day oral toxicity studies in rats and dogs. The agency has evaluated the studies and concludes that the studies showed no evidence of toxicity or genotoxicity (Ref. 16).

Finally, Pfizer, Inc., presented information regarding use levels of the enzyme preparation in milk and milk products. Based on this information, the agency concludes that the use of lactase enzyme preparation from *C. pseudotropicalis* would not add to the total consumption of lactase from all sources because the petitioned enzyme preparation will be substituted for other lactase enzyme preparations currently in use (Ref. 17).

VI. Conclusions

The agency has evaluated the information in the petition, along with other available information, and concludes that lactase enzyme preparation derived from *C. pseudotropicalis* is GRAS. This conclusion is based on published information, corroborated by unpublished data and information.

Therefore, the agency is affirming that lactase enzyme preparation derived from *C. pseudotropicalis* is GRAS with no limits on its conditions of use other than current good manufacturing practice, in accordance with 21 CFR 184.1(b)(1). This GRAS affirmation is based on evaluation of the use of the enzyme preparation to reduce the lactose content of milk and milk-derived food products.

The agency further finds that because the principal active ingredient of the enzyme preparation is safe and because expected impurities in the enzyme preparation do not provide any basis for a safety concern, the general requirements and additional requirements for enzyme preparations given in the Food Chemicals Codex, 3d ed. (1981), pp. 107–110, are adequate as minimum criteria for food-grade lactase enzyme preparations derived from *C. pseudotropicalis*.

VII. Environmental Impact

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.

VIII. Analysis of Impacts

FDA has examined the impact of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is significant if it meets any one of a number of conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or raising novel legal or policy issues. The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses.

FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. The final rule does not raise novel legal or policy

issues. The compliance cost to firms currently in the industry is zero because the rule prohibits no current activity. Potential benefits include the wider use of the enzyme preparation because of reduced uncertainty concerning its regulatory status, and any resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of this use of the enzyme preparation.

Finally, in compliance with the Regulatory Flexibility Act, FDA certifies that the final rule will not have a significant impact on a substantial number of small businesses. The compliance cost to small businesses currently in the industry is zero because no current activity is prohibited under the rule.

IX. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act (5 U.S.C 553(d)). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

X. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Lodder, J., *The Yeasts: A Taxonomic Study*, 2d ed., pp. 345–348, 1025–1027, North Holland Publishing Co., Amsterdam, 1970.

2. Rose, A. H., and J. S. Harrison, *The Yeasts, V 1, Biology of Yeasts*, p. 139, Academic Press, New York, 1969.

3. 21 CFR 184.1388.

4. ''Monograph on Enzyme Preparations,'' in *Food Chemicals Codex*, 3d ed., National Academy Press, Washington, DC, pp. 107–110, 1981.

5. Schmidt, J. L., and J. Lenoir, ''Contribution to the Study of Yeast Flora in Camembert Cheese. Its Development During Ripening,'' *Lait* 58 (577):355–370, 1978.

6. Kreger van Rij, N. J. W., ''*The Yeasts: A Taxonomic Study*,'' pp. 233–234, North Holland Pub. Co., Amsterdam, 1970.

7. Lutwick, L. I., H. J. Phaff, and D. A. Stevens, ''*Kluyveromyces fragilis* as an Opportunistic Fungal Pathogen in Man,'' *Sabouraudia* 18:69–73, 1980.

8. Yamazaki, M., and K. Komagata, ''Asporogenous Yeasts and Their Supposed Ascosporogenous States: An Electrophoretic Comparison of Enzymes,'' *Journal of General and Applied Microbiology*, 28:119–138, 1982.

9. Letter from H. J. Phaff, University of California, Davis, to W. C. Wernau, Pfizer, Inc., February 13, 1980.

10. Memorandum from T. J. McKay, FDA, to M. Custer, FDA, November 8, 1982.

11. Memorandum from C. B. Johnson, FDA, to N. Beru, FDA, February 2, 1994.

12. Memorandum from C. B. Johnson, FDA, to the Direct Additives Branch, FDA, December 6, 1988.

13. Holzschu, D. L. et al., ''Evaluation of industrial yeast for pathogenicity,'' *Sabouraudia* 17:71–78, 1979.

14. Memorandum from P. Mislivec, FDA, to M. Custer, FDA, October 22, 1982.

15. Memorandum from J. M. Madden, FDA, to M. Peiperl, FDA, November 5, 1993.

16. Memorandum from A. N. Milbert, FDA, to V. Prunier, FDA, August 13, 1984.

17. Memorandum from J. Modderman, FDA, to V. Prunier, FDA, November 7, 1984.

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. New § 184.1387 is added to subpart B to read as follows:

§ 184.1387 Lactase enzyme preparation from Candida pseudotropicalis.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic yeast *C. pseudotropicalis*. It contains the enzyme lactase (β-D-galactoside galactohydrolase, EC 3.2.1.23), which converts lactose to glucose and galactose. It is prepared from yeast that has been grown by a pure culture fermentation process.

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), pp. 107–110, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in § 170.3(o)(9) of this chapter, to convert lactose to glucose and galactose.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice is limited to use of this ingredient to reduce the lactose content in milk and milk-derived food products where food standards do not preclude such use.

Dated: February 15, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–4629 Filed 2–28–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 81

[AG Order No. 2009–96]

RIN 1105–AA38

Designation of Agencies To Receive and Investigate Reports Required Under the Victims of Child Abuse Act

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This rule carries out the Attorney General's responsibilities under the child abuse reporting provisions of the Victims of Child Abuse Act of 1990 (''VCAA''). The VCAA requires persons engaged in certain specified professions and activities on federal lands or facilities to report incidents of child abuse to the appropriate federal, state, or local agency designated by the Attorney General. In order to facilitate effective reporting, the VCAA requires the Attorney General to ''designate an agency'' to receive and investigate such reports of child abuse. This rule sets forth the Attorney General's designations and certain other matters covered by the VCAA's reporting requirements.

EFFECTIVE DATE: This rule is effective April 1, 1996.