purpose. To preclude entry of moisture into the honeycomb area it is necessary to seal each blind fastener in the upper surface of the fuel bay upper panel on all affected airplanes, regardless of condition.

Since the FAA has determined that the unsafe conditon described herein is likely to exist or develop in other airplanes of the same type design, an AD is being issued requiring inspection and repair of upper wing panels on certain Beech 200 series airplanes. Because an emergency condition exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impractical and contrary to the public interest, and good cause exists for making this amendment effective in less than 30 days.

Note.—The FAA has determined that this regulation is an emergency regulation that is not major under Section 8 of Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979). If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, when filed, may be obtained by contacting the Rules Docket under the caption **"ADDRESSES"** at the location identified.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of the Federal Aviation Regulations (14 CFR Section 39.13) is amended by adding the following new AD.

Beech: Applies to Models 200 and B200 (serial nos. BB–614 thru BB–1192 except BB–627, BB–647 BB–665, BB–798, BB–823, BB–1139, BB–1158, BB–1167, BB–1179, and BB–1189); 200C and B200C (serial nos. BL–7 thru BL–66 and BL–68 thru BL–71); 200 CT and B200CT (serial nos. BN–1 thru BN–4); 200T and B200T (serial nos. BT–20 thru BT–26, BT–28, and BT–30); C–12D and FWC–12D (serial nos. BP–1, BP–7 thru BP–11, BP–22, and BP–24 thru BP–45); RC–12D (serial nos. GR–1 thru GR–10); and UC–12B (serial nos. BJ–1 thru BJ–66) airplanes certificated in any category.

Compliance: Required within the next 75 hours time-in-service or six calendar months, whichever occurs first, after the effective date of this AD, unless already accomplished:

To assure the continued structural integrity of the wing fuel bay upper panels, accomplish the following:

(a) Inspect the wing center section upper skin panels for possible debonding in accordance with Beech Service Bulletin No. 2040 (for civil registered airplanes) or Beech Service Instructions No. C–12–0094 (for military airplanes).

(1) If no debonding is detected, proceed to paragraph (b) below.

(2) If debonding is detected in either panel, the discrepant panel must be repaired by installation of Kit No. 101–4032–1 (L.H.) or 101–4032–3 (R.H.), prior to proceeding to paragraph (b) below.

(b) Seal all accessible blind rivets in both wing center section fuel bay upper panels as described in Service Bulletin 2040 or Service Instructions C–12–0094 (as applicable).

(c) Airplanes may be flown in accordance with FAR 21.197 to a location where the AD may be accomplished.

(d) An equivalent means of compliance with this AD may be used, if approved by the Manager, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; Telephone (316) 946–4400.

(Secs. 313(a), 601 and 603 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421 and 1423); 49 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12, 1983); Sec. 11.89 of the Federal Aviation Regulations (14 CFR Sec. 11.89))

This amendment becomes effective on December 11, 1984.

Issued in Kansas City, Missouri, on November 23, 1984.

John E. Shaw,

Acting Director, Central Region.

[FR Doc. 84–31570 Filed 12–3–84; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 39

[Docket No. 84–NM–126–AD; Amdt. 39–4960]

Airworthiness Directives: BFGoodrich Emergency Evacuation Slide/Rafts P/N's 7A1340 Series, 7A1342 Series, 7A1371 Series, 7A1373 Series, 7A1437 Series, 7A1439 Series, 7A1447 Series, and 7A1448 Series, Installed in Boeing Model 747 Airplanes in Accordance With Supplemental Type Certificates (STC) SA574GL, SA575GL, SA744GL, or SA745GL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) which requires the inspection and replacement of girt bar attachment assemblies of BFGoodrich Emergency Evacuation Slide/Rafts installed in certain Boeing Model 747 airplanes in accordance with supplemental type certificates. This AD is prompted by the failure of a girt bar attachment assembly during an emergency evacuation. The inspection and replacement procedure contained in this amendment are necessary to prevent additional failures of these slides/rafts when needed during an emergency evacuation of the airplane.

DATES: Effective December 17, 1984.

Compliance is required within 15 days after the effective date of this AD, unless already accomplished.

ADDRESSES: The applicable service bulletin may be obtained from BFGoodrich Company, Attn: Mr. David Smith, Dept. 1809, Bldg. 17F, 500 South Main Street, Akron, Ohio 44318; telephone (216) 374–2886. A copy of the service bulletin is contained in the Rules Docket, Office of the Regional Counsel, FAA, Northwest Mountain Region, 17900 Pacific Highway South, C–68966, Seattle, Washington, 98168.

FOR FURTHER INFORMATION CONTACT: Charles Smalley, Aerospace Engineer, Systems Equipment Branch, ACE–130C, FAA, Central Region, Chicago Aircraft Certification Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018; telephone (312) 694–7126.

SUPPLEMENTARY INFORMATION: During an emergency evacuation of a Boeing Model 747 airplane on November 16, 1984, the slide/raft installed at door Number One Left became detached and fell from the aircraft. Several passengers were using the slide/raft as it fell to the ground; one passenger required hospitalization as a result of injuries sustained during the fall. It was found that the thread holding the loops to the girt bar attachment assembly broke, which allowed the slide/raft to fall from the aircraft. A second slide/raft on the airplane which had the same style girt bar attachment assembly began to exhibit the same failure mode while being buffeted by the wind after the evacuation was completed. This style girt bar attachment assembly has been replaced with a new style on the currently manufactured slide/rafts. To prevent additional failures of this type, an airworthiness directive is being issued which requires the replacement of the old style girt bar attachment assemblies on BFGoodrich Emergency Evacuation Slide/Rafts, P/N's 7A1340 series, 7A1342 series, 7A1371 series, 7A1373 series, 7A1437 series, 7A1439 series, 7A1447 series, and 7A1448 series.

Since a situation exists which requires immediate adoption of this amendment, it is found that notice and public procedure hereon are impracticable and

good cause exists for making this AD effective in less than 30 days.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, Section 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new airworthiness directive:

BFGoodrich: Applies to BFGoodrich Emergency Evacuation Slide/Rafts P/N's 7A1340 series, 7A1342 series, 7A1371 series, and 7A1373 series installed on Boeing Model 747–100 and 747–200B airplanes in accordance with Supplemental Type Certificate (STC) SA574GL, and on Boeing Model 747–100B, 747SR, and 747–300 airplanes in accordance with STC SA575GL; and BFGoodrich Emergency Evacuation Slide/Rafts P/N's 7A1437 series, 7A1439 series, 7A1447 series, and 7A1448 series installed on Boeing Model 747–100 and 747–200B airplanes in accordance with STC SA744GL, and on Boeing Model 747–100B, 747SR, and 747–300 airplanes in accordance with STC SA745GL.

Compliance is required as indicated, unless already accomplished.

Inspect and replace, as required, the girt bar attachment assemblies in accordance with the following:

A. Within the next 15 days after the effective date of this airworthines directive (AD), inspect the applicable slide/rafts and replace the girt bar attachment assemblies in accordance with the procedures contained in BFGoodrich Alert Service Bulletin 25–093, Revision 1, dated November 21, 1984, or subsequent FAA approved revisions.

B. Destroy the replaced girt bar attachment assemblies to preclude their installation at a later date.

C. Alternate means of compliance with this AD which provide an equivalent level of safety may be used when approved by the Manager, Chicago Aircraft Certification Office, FAA, Central Region.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to BFGoodrich Company, Attn: Mr. David Smith, Dept. 1809, Bldg. 17F, 500 South Main Street, Akron, Ohio 44318; telephone (216) 374–2886. These documents also may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington.

This amendment becomes effective December 17, 1984.

(Secs. 313(a), 314(a), 601 through 610, and 1102 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 through 1430, and 1502); 49 U.S.C 106(g) (Revised, Pub. L 97–449, January 12, 1983); and (14 CFR 11.89)

Note.—The FAA has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft equipment. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; Feburary 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption **"FOR FURTHER INFORMATION CONTACT."**

Issued in Seattle, Washington, on November 27, 1984.

Wayne J. Barlow,

Acting Director, Northwest Mountain Region.

[FR Doc. 84–31572 Filed 12–3–84; 8:45 am]

BILLING CODE 4910–13–M

TENNESSEE VALLEY AUTHORITY

18 CFR Part 1302

Nondiscrimination In Federally Assisted Programs of TVA; Effectuation of Title VI of the Civil Rights Act of 1964; Correction

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Final rule; correction.

SUMMARY: This document corrects a number of errors contained in the final rule amending Part 1302 of TVA's regulations which was published May 15, 1984 (49 FR 20480). Part 1302 implements the requirements of Title VI of the Civil Rights Act of 1964, as amended, insofar as that title applies to programs which receive financial assistance from TVA. The corrections to the final rule were suggested by the Department of Justice and the Office of the Federal Register.

FOR FURTHER INFORMATION CONTACT: William L. Osteen, Jr., Associate General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, Knoxville, Tennessee 37902, (615) 632–4142.

DATED: November 27, 1984.

W. F. Willis,

General Manager.

PART 1302—[AMENDED]

Accordingly, TVA is correcting the amendments to 18 CFR Part 1302, which appeared as FR Doc. 84–12967 at pages 20480–4 in the issue of May 15, 1984, as follows:

§ 1302.13 Definitions [Redesignated as § 1302.3]

1. By redesignating § 1302.13 (appearing at page 20481, column one) as § 1302.3 and by correcting it by adding quotations marks to the terms defined in paragraphs (a)–(d) as follows:

* * * * *

(a) "TVA" * * *

(b) "Recipient" * * *

(c) "Assistant Attorney General" * * *

(d) "Title VI" * * *

§ 1302.7 Compliance reviews and conduct of investigations.

2. By correcting § 1302.7 by changing the reference to "paragraph (b)(5)" to "paragraph (b)(6)" where it appears in § 1302.7(b)(3)(iii) in column two of page 20482; by ending paragraph (b)(4) (page 20482, column two) with paragraph (iii), the end of which is revised to read "* * * made." instead of "* * * made; and,"; and by redesignating paragraph (b)(4)(iv) as paragraph (b)(5), and revising the paragraph to read as follows:

* * * * *

(b) * * *

(5) TVA's General Manager may extend the 180-day period set out in paragraph (b)(4) of this section for good cause shown.

In addition, § 1302.7 is further corrected by redesignating paragraphs (b)(5), (b)(6), and (b)(7) (page 20482, columns two and three) as paragraphs (b)(6), (b)(7), and (b)(8), respectively. Furthermore, the last sentence of § 1302.7(c)(4) (page 20483, column one) now reads:

* * * * *

(c) * * *

(4) * * * The determination is to be made no later than 14 days after conclusion of a 50-day negotiation period, whenever possible.

* * * * *

The last sentence of § 1302.7(c)(4) is corrected to read:

* * * * *

(c) * * *

(4) * * * The determination is to be made no later than 14 days after conclusion of a 50-day negotiation

period. TVA's General Manager may extend the 14-day period for good cause shown.

* * * * *

§ 1302.8 Procedure for effecting compliance.

3. By correcting paragraph (b) of § 1302.8 (page 20483, column two) by adding the following phrase to the end of the paragraph:

* * * * *

(b) * * * and for such purposes, the term "recipient" shall be deemed to include one which has been denied financial assistance.

* * * * *

§ 1302.10 [Redesignated as § 1302.11]

4. By redesignating § 1302.10 as § 1302.11.

[FR Doc. 84-31668 Filed 12-3-84; 8:45 am]
BILLING CODE 8120-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 632

Job Training Partnership Act: Indian and Native American Employment and Training Programs; Correction

AGENCY: Employment and Training Administration, Labor.

ACTION: Final designation procedures for grantees; correction.

SUMMARY: This document corrects a rule-related notice that appeared in the **Federal Register** of Tuesday, October 23, 1984. The wording at page 42561 incorrectly appeared to permit all applicants to request to serve only the members of specific tribes, rather than all Native Americans residing in an area.

EFFECTIVE DATE: October 23, 1984.

FOR FURTHER INFORMATION CONTACT: Mr. Paul A. Mayrand, Director, Office of Special Targeted Programs, 601 D Street, NW, Room 6122, Washington, D.C. 20213. Phone: (202) 376-6225.

SUPPLEMENTARY INFORMATION: The following corrections are made in **Federal Register** Doc. 84-27925 appearing on page 42559 in the issue of October 23, 1984:

On page 42561, Section II of the notice contained instructions for requesting specific population groups within a county and a sample county described as "Beaumont (only members of Aztec Tribe)." The Department of Labor wishes to make it known that these references were intended to apply only to States of Oklahoma and Hawaii. Grantees in all other States are required to serve all eligible Native Americans residing in their assigned areas. The Department has maintained this policy for many years for the purposes of avoiding fragmentation of geographic areas.

This policy was restated clearly in the referenced **Federal Register** notice, under **SUPPLEMENTARY INFORMATION.** It applies whether the area is an entire county, only the reservation part of a county, or only the off-reservation part of a county. Applicants should be cognizant of this when preparing their final Notice of Intent under 20 CFR 632.11, which must be postmarked by January 1, 1985 or delivered no later than close of business on January 2, 1985.

Signed at Washington, D.C. this 27th day of November 1984.

Paul A. Mayrand,

Director, Office of Special Targeted Programs.

[FR Doc. 84-31646 Filed 12-3-84; 8:45 am]
BILLING CODE 4510-30-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 77G-0007]

Direct Food Substances Affirmed as Generally Recognized as Safe; Lactase Enzyme Preparation From Kluyveromyces Lactis

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that a lactase enzyme preparation derived from the yeast *Kluyveromyces lactis* is generally recognized as safe (GRAS) for use in the production of lactase-treated milk and lactose-reduced milk. This action responds to a petition filed by SugarLo Co.

DATES: Effective December 4, 1984. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1388 effective on December 4, 1984.

FOR FURTHER INFORMATION CONTACT: Damon Larry, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION:

Introduction

Under the procedures described in § 170.35 (21 CFR 170.35), SugarLo Co., P.O. Box 1017, Atlantic City, NJ 08404, submitted a petition (GRASP 6G0077), requesting that FDA affirm as GRAS the use of a lactase enzyme preparation derived from the yeast *Kluyveromyces lactis* (*K. lactis*) (previously named *Saccharomyces lactis)* to produce lactase-treated milk, in which there is less lactose than regular milk, and lactose-reduced milk, in which 70 percent or more of the lactose has been converted to glucose and galactose.

FDA published a notice of the filing of this petition in the **Federal Register** of April 19, 1977 (42 FR 20348), and gave interested persons an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. FDA did not receive any comments in response to that notice. However, on April 30, 1979, a manufacturer of lactase enzyme preparations submitted a number of published reports on the occurrence of *K. lactis* in food to augment the safety data in the petition. FDA considers this submission to be a comment on the petition and has reviewed the reports submitted in the comment in its evaluation of the petition.

Lactase enzyme preparation from *K. lactis* is a soluble enzyme preparation. It is composed of the cellular fraction of *K. lactis* that contains lactase enzyme activity, residual amounts of processing aids used to separate this cellular fraction from the yeast cells, and substances added to this cellular fraction as stabilizers or diluents. The lactase enzyme preparation contains the enzyme B-galactoside galactohydrase which catalyzes the hydrolysis of the disaccharide lactose to the monosaccharides glucose and galactose.

Lactase enzyme preparation from *K. lactis* has been commercially available to food processors in the United States since 1972 and since 1976 has been sold at the retail level for home use. This enzyme preparation also has been used experimentally in the United States in the manufacture of cheese. Lactose-reduced milk prepared from lactase enzyme preparation from *K. lactis* has been sold in some U.S. markets since 1978.

In evaluating this petition to affirm as GRAS the use of lactase enzyme preparation from *K. lactis* as a food ingredient, the agency has considered five aspects of its manufacture and use: (1) The source of the lactase enzyme

preparation, (2) the production and purification of the lactase enzyme preparation, (3) the use of the lactase enzyme preparation in food, (4) residual levels of the lactase enzyme preparation that may occur in the food, and (5) the safety of the lactase enzyme preparation and of the resulting hydrolyzed lactose (i.e., lactose that has been enzymatically converted to glucose and galactose).

Source of Lactase Enzyme Preparation

1. The source of this enzyme preparation is the yeast *K. lactis*. According to published reports included in the petition or submitted in the comment on the petition, *K. lactis* has been isolated from yogurt, certain cheeses, and fermented milks such as kefir. Published information shows that *K. lactis* appears to act synergistically with bacteria in yogurt culture. In addition, during cheese culture, *K. lactis* produces carbon dioxide, which is necessary to open the cheese (that is, to create air pockets in the cheese) before brining. This information shows that *K. lactis* is a normal, even necessary, constituent of many cultured dairy products. Published information in the petition also shows that the morphology life-cycle, and nutritional requirements of *K. lactis* have been well-characterized.

Production and Purification of the Lactase Enzyme Preparation

2. The methods by which microbial lactase enzyme preparations are made have been the subject of numerous scientific reviews (e.g., Refs. 1 through 4). Methods of partially purifying lactase enzyme preparations from various species of *Kluyveromyces*, including *K. lactis*, are described in Refs. 5 and 6.

The petition describes the commercial production of lactase enzyme preparation from *K. lactis*. Under the method of manufacture described in the petition, *K. lactis* is maintained as a pure culture under conditions that minimize any genetic changes and is grown in a pure culture fermentation. At the end of the fermentation, the cells are collected, washed with water, and ruptured with octanol. The insoluble cellular fragments are removed from the liquid fraction and discarded. Ethanol is then added to the liquid fraction to solidify the proteins, which include the enzyme. This insoluble material is separated from the liquid, washed with ethanol, and dried. Under this method of manufacturing this enzyme preparation, the processing aids used to separate the cellular fraction of the yeast cell that contains the enzyme activity and the substances added to this cellular fraction to stabilize or dilute the enzyme preparation are either GRAS ingredients or approved food additives.

The petition shows that the enzyme preparation produced by this method of manufacture does not contain any viable yeast cells. It also shows that lactase enzyme preparation from *K. lactis* produced in this manner meets the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d Ed. (1981), and that this substance catalyzes the reaction described for lactase in the Food Chemicals Codex. The petition further shows that when lactase enzyme preparation from *K. lactis* is made under the method of manufacture that it describes, there is little variation in the specific activities of individual batches of enzyme preparation.

The Use of Enzyme Lactase Preparation in Food

3. Lactase enzyme preparation from *K. lactis* is added to milk to convert the lactose in the milk to glucose and galactose. Milk treated with the preparation therefore contains less lactose than regular milk. Milk with a reduced lactose content is sold to people with lactose intolerances.

Residual Levels of Lactase Enzyme from K. lactis That May Occur in Food

4. The petition contains information showing that the use of lactase enzyme preparation from *K. lactis* under current good manufacturing conditions to produce lactose-reduced milk results in levels of the enzyme preparation ranging up to 375 parts per million in the finished food.

According to the information in the petition, the level of the enzyme preparation from *K. lactis* used will vary depending upon the degree of hydrolysis desired, the incubation conditions, and the duration of incubation. Data in the petition show that the enzymatic activity of lactase enzyme preparation from *K. lactis* declines under acidic conditions and ceases when this lactase enzyme preparation is exposed to pH below 2. These data also demonstrate that this enzyme preparation shows maximal activity in the temperature range of 25 to 40 °C. The enzymatic activity of this enzyme preparation decreases at temperatures below 25 °C and ceases at temperatures of 60 °C or above.

According to information in the petition, mixtures of lactase enzyme preparation from *K. lactis* may be incubated at 35 °C for 6 hours or less or at refrigeration temperatures (i.e., 7 °C or below) for 24 hours or more to produce lactose-reduced milk, in which at least 70 percent of the lactose is converted to glucose and galactose. If a lesser degree of lactose hydrolysis is desired, adjustments may be made in the level of lactase enzyme preparation that is added to the milk or in the length of the incubation of the mixture of milk and lactase enzyme preparation.

The variability of the conditions of use for lactase enzyme preparation from *K. lactis* suggests that there are no typical levels of use for this preparation. Aside from the finding that use of the enzyme preparation will result in no more than 375 parts per million of the enzyme preparation in the finished food, there is no set of percentage-by-weight use levels for addition of this lactase enzyme preparation to food that would be applicable under the wide variety of conditions under which this enzyme product is used.

Safety of Use of Lactase Enzyme Preparation and of the Resulting Hydrolyzed Lactose

5–A. The petition contains unpublished animal feeding studies of lactase enzyme preparation from *K. lactis* that show that this enzyme preparation was not harmful under the conditions of the test. However, FDA finds that the design of these animal feeding studies does not meet the criteria established in the "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food" (1982). Therefore, these animal feeding studies do not constitute sufficient evidence to support the petition.

FDA nonetheless finds that sufficient information is available to establish the safety of lactase enzyme preparation from *K. lactis*. The agency is basing this finding on evidence that the yeast *K. lactis* is safe, evidence that the materials used to make the enzyme preparation are safe, and information about the amount of exposure to this lactase enzyme preparation and to dried *K. lactis* yeast.

Safety of the Yeast

5–B. The comment on GRASP 6G0077 contains published information that establishes the safety of the yeast *K. lactis*. Among this published information is information that establishes that *K. lactis* is a normal, even necessary component of many cultured dairy products, and that no reports of toxicity or pathogenicity have ever been associated with the presence of *K. lactis* in food (Refs. 7 and 8). Additionally, the comment includes published studies in which subjects were fed 10 grams or more per day of dried *K. lactis* as a dietary supplement in a variety of

clinical situations (Refs. 9 and 10). These studies also did not reveal any health hazard attributable to the consumption of dried *K. lactis*. Finally, FDA is aware that dried *K. lactis* is consumed as a dietary supplement in Europe (Ref. 9).

Safety of Materials Used to Make the Enzyme Preparation

5–C. FDA finds that the process of extracting the lactase-containing cellular fraction of *K. lactis* during the manufacture of the lactase enzyme preparation does not create any basis for concern about the safety of the preparation. As discussed in paragraph 2 above, the cellular fraction of the yeast that contains lactase enzyme activity is separated from the yeast cell by physical means. As explained in paragraph 2, under the conditions described in the petition, the solvents used in the extraction of the lactase-containing cellular fraction of *K. lactis* are unlikely to change the cellular fraction in any chemically significant way. Moreover, as stated above, information in the petition shows that the substances used to extract the cellular fraction or to stabilize or to dilute the lactase enzyme preparation are either GRAS ingredients or food additives approved for this use.

Exposure Data

Use information contained in the petition domonstrates that consumption of the lactase enzyme preparation from *K. lactis* (including diluents and stabilizers as well as cellular material derived from *K. lactis*) resulting from its use in milk will not exceed 250 milligrams per person per day (Ref. 11). Even if it is assumed that the entire enzyme preparation is composed of cellular material, this amount of cellular material is much less than the amount of such cellular material that was consumed by the subjects in the clinical studies of the use of dried *K. lactis* as a dietary supplement (Refs. 9 and 10). Thus, because the level of exposure to this cellular material from consuming dried *K. lactis* as a dietary supplement is safe, and because that exposure is much greater than the level of exposure to the cellular material that results from the consumption of milk treated with lactase enzyme preparation from *K. lactis*, FDA concludes that the levels of lactase enzyme preparation from *K. lactis* used in the production of lactase-treated and lactose-reduced milk are safe.

Other Information

The petition also contains published clinical studies on the consumption of lactose-reduced milk that has been prepared with this enzyme preparation. These studies show that lactose-reduced milk, which contains residual amounts of the enzyme preparation, has been ingested by lactose intolerant people without ill effects. Data in the petition also show that the monosaccharides galactose and glucose occur in equal proportions in lactose-reduced milk, and that the quantity of glucose and galactose in lactose-reduced milk does not exceed the quantity of these monosaccharides derived from lactose that is ingested when an equal volume of regular milk is consumed. FDA finds that this information corroborates its conclusion that lactase enzyme preparation from *K. lactis* is safe for use in the production of lactase-treated milk and lactose-reduced milk.

Conclusions

The agency has evaluated all the information related to the use of lactase enzyme preparation from *K. lactis* and has reached the following conclusions:

1. The enzyme preparation is not GRAS based upon history of common use in food.

2. The enzyme preparation is GRAS based upon scientific procedures. This conclusion is based upon FDA's evaluation of information provided in published studies that relate to the safety of the yeast *K. lactis*, the procedures used to produce the enzyme preparation, and the safety of milk that has been treated with the enzyme product.

3. Lactase enzyme preparation from *K. lactis* is technically effective for producing lactase-treated milk or lactose-reduced milk.

4. It is both impractical and unnecessary for FDA to delineate the levels of lactase enzyme preparation from *K. lactis* used in milk. FDA has determined that the amount of active enzyme that is added to milk is variable because of the variable conditions of use, and that a set of percentage-by-weight levels of use for lactase enzyme preparation would not be useful. In addition, there are no safety concerns to warrant establishment of use levels for lactase enzyme preparation from *K. lactis*.

Therefore, the agency is affirming that lactase enzyme preparation from *K. lactis* is GRAS when used under current good manufacturing practice conditions in accordance with § 184.1(b)(1). To make clear, however, that the affirmation of the GRAS status of this substance is based on the evaluation of limited uses, the regulation sets forth the technical effect and food uses of this ingredient that FDA evaluated.

Environmental Effects

The agency has determined pursuant to 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Economic Effects

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule, and the agency has determined that the rule is not a major rule as defined by that Order. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

References

The following information has been placed on display with the Dockets Management Branch (address above).

1. Pomeranz, Y., "Lactase (Beta-D-Galactosidase) I. Occurrence and Properties," *Food Technology*, 88:682–687, 1964.

2. Wallenfels, K., and O.P. Malhorta "B-Galactosidase (Crystalline)," *in* "Methods in Enzymology," Vol. V, S.P. Colowick and N.O. Kaplan, eds., Academic Press, New York, pp. 212–219, 1960.

3. Underkofler, L.A., R.R. Barton, and S.S. Rennert, "Microbiological Process Report," *Applied Microbiology*, 6:212–221, 1958.

4. Beckhorn, E.J., M.D. Labbee, and L.A. Underkofler, "Production and Use of Enzymes for Food Processing," *Journal of Argiculture and Food Chemistry*, 13:30–34, 1965.

5. Beirmann, L. and M.D. Glantz, "Isolation and Characterization of B-Galactosidase from *Saccharomyces lactis*," *Biochimica et Biophysica Acta*, 1:67:373–377, 1968.

6. Fenton, D.M., "Solvent Treatment for B-D-Galactosidase Release from Yeast Cells," *Enzyme Microbiological Technology* 4:229–232, 1982.

7. Memorandum dated December 13, 1983, from P. Mislivec to S. Shibko, "*Saccharomyces lactis* Lactase Enzyme."

8. Memorandum dated June 5, 1978, from P. Mislivec to V. Prunier, "Lactase Enzyme Derived from *Kluyveromyces lactis*."

9. Vrignaud, Y., "Levure Lactique," *Revue de Institut Pasteur de Lyon*, 4:147–165, 1971, translation provided by G.B. Fermentation Industries, Inc., as part of a comment on GRASP 6G0077.

10. Gervais, Cl., "Effet bénéfique d'une levure lactique chez l'enfant Biafrais dénutri," *Bulletin de la Société de Pathologie Exotique*, 66:445–450, 1973, translation provided by G.B. Fermentation Industries, Inc., as part of a comment on GRASP 6G0077.

11. Memorandum date March 15, 1976, from L.W. Schroeder to V.G. Prunier, "Review of

Submissions of 1–19–78 and 12/5/77 Lactose Enzyme (LE) from *Kluyveromyces lactis.*"

List of Subjects in 21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 184 is amended by adding new § 184.1388, to read as follows:

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

§ 184.1388 Lactase enzyme preparation from Kluyveromyces lactis.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic yeast *Kluyveromyces lactis* (previously named *Saccharomyces lactis).* It contains the enzyme B-galactoside galactohydrase (CAS Reg. No. CBS 683), which converts lactose to glucose and galactose. It is prepared from yeast that has been grown in a pure culture fermentation and by using materials that are generally recognized as safe or are food additives that have been approved for this use by the Food and Drug Administration.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d Ed. (1981), p. 107–110, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation 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 to use this ingredient in milk to produce lactase-treated milk, which contains less lactose than regular milk, or lactose-reduced milk, which contains at least 70 percent less lactose than regular milk.

Effective date. This regulation shall become effective December 4, 1984.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: November 5, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84–31583 Filed 12–3–84; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 510

New Animal Drugs; Change of Sponsor Name

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a sponsor name change for several new animal drug applications (NADA's) from Byk-Gulden, Inc., to Altana, Inc.

EFFECTIVE DATE: December 4, 1984.

FOR FURTHER INFORMATION CONTACT: John W. Borders, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6243.

SUPPLEMENTARY INFORMATION: Byk-Gulden, Inc., 60 Baylis Rd., Melville, NY 11747, advised the Center for Veterinary Medicine of a change in corporate name to Altana, Inc. This is an administrative change which does not in any other way affect the approval of the firm's NADA's. The regulations in 21 CFR 510.600(c) are amended accordingly.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.83), Part 510 is amended in § 510.600 in paragraph (c)(1) by removing the entry for "Byk-Gulden, Inc.," and by alphabetically adding a new entry for "Altana, Inc.," and in paragraph (c)(2) in the entry for "025463" by removing the sponsor name "Byk-Gulden, Inc.," and inserting in its place "Altana, Inc.," to read as follows:

PART 510—NEW ANIMAL DRUGS

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Altana, Inc., 60 Baylis Rd., Melville, NY 11747	025463
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
025463	Altana, Inc., 60 Baylis Rd., Melville, NY 11747
* * * * *	

Effective date. December 4, 1984.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: November 26, 1984.

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 84–31584 Filed 12–3–84; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 558

Animal Drugs, Feeds, and Related Products; Change of Sponsor

Correction

In FR Doc. 84–26551 beginning on page 39539 in the issue of Tuesday, October 9, 1984, make the following correction:

On page 39539, third column, under "Part 558", "§ 558.321" should have read "§ 558.325".

BILLING CODE 1505–01–M

21 CFR Part 1020

[Docket No. 76N–0308]

Diagnostic X-Ray Systems and Their Major Components; OMB Approval and Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Office of Management and