

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 galactohydase 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 demonstrates 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*, 68:682-687, 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*, 8:212-221, 1956.
4. Beckhorn, E.J., M.D. Labbee, and L.A. Underkofler, "Production and Use of Enzymes for Food Processing," *Journal of Agriculture 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. Vignaud, Y., "Levure Lactique," *Revue de l'Institut Pasteur de Lyon*, 4:147-165, 1971, translation provided by G.B. Fermentation Industries, Inc., as part of a comment on GRASP 6C0077.
10. Gervais, Cl., "Effet bénéfique d'une levure lactique chez l'enfant Bialfrais 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 6C0077.
11. Memorandum dated March 15, 1978, 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 galactohydase (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 5.33), 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 28, 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

Budget (OMB) has approved the information collection requirements in the final rule amending the performance standard for diagnostic x-ray systems and their major components to add requirements concerning computed tomography x-ray (CT) systems. FDA also is affirming the effective date of the amendments.

EFFECTIVE DATE: September 3, 1985, except for § 1020.30 (a), (b)(36)(iii)-(v), (58)-(62), (h)(3)(iv)-(viii), and (n); §§ 1020.31 and 1020.32 (introductory texts); § 1020.33 (a), (b), and (c)(2); and § 1020.33(c)(1) as it affects § 1020.33(c)(2), all of which are effective November 29, 1984.

FOR FURTHER INFORMATION CONTACT: Joseph Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 31, 1984 (49 FR 34698), FDA published a final rule amending the performance standard for diagnostic x-ray systems and their major components (21 CFR 1020.30, 1020.31, and 1020.32) and adding new requirements in 21 CFR 1020.33. The final rule adds new provisions to the standard to address the radiation safety aspects of CT systems. The rule requires manufacturers of CT systems to provide user information to purchasers of CT systems concerning conditions of use, dose, and imaging.

OMB Approval

In paragraph 78 of the preamble to the final rule, FDA advised that the collection of information requirements contained in § 1020.33 (c), (d), (g), and (j) would be submitted to OMB for approval under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). The agency also stated that the requirements under § 1020.33 (c), (d), (g), and (j) would not be effective until FDA obtained OMB approval of these information collection requirements. FDA also advised that it would publish a notice in the Federal Register concerning OMB approval of the requirements.

On October 24, 1984, OMB approved without change the collection of information requirements, under OMB control number 0910-0025.

List of Subjects in 21 CFR Part 1020

Electronic products, Ionizing radiation, Medical devices, Radiation protection, Standards, Television receivers, X-rays.

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

§ 1020.33 [Amended]

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f) and under the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 701, 52 Stat. 1040-1042 as amended, 1049-1051 as amended, 1055-1056 as amended (21 U.S.C. 321, 351, 352, 371)) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 1020 is amended in § 1020.33 *Computed tomography (CT) equipment* in paragraphs (c), (d), (g), and (j) by adding the number "0910-0025" at the end of the parenthetical statement appearing at the end of each paragraph.

Effective date. This regulation shall be effective September 3, 1985, except for the following, which shall be effective November 29, 1984: § 1020.30 (a), (b)(36)(iii)-(v), (58)-(62), (h)(3)(vi)-(viii), and (n); §§ 1020.31 and 1020.32 (introductory texts); § 1020.33 (a), (b), and (c)(2); and § 1020.33(c)(1) as it affects § 1020.33(c)(2).

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f); secs. 201, 501, 502, 701, 52 Stat. 1040-1042 as amended, 1049-1051 as amended, 1055-1056 as amended (21 U.S.C. 321, 351, 352, 371))

Dated: November 27, 1984.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-31582 Filed 11-29-84; 10:43 am]

BILLING CODE 4160-01-W

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Part 234

[Docket No. R-84-1215; FR-2030]

Condominium Mortgage Insurance: Maximum Mortgage Amounts for Nonoccupant Mortgagors

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This rule amends the Department's regulation prescribing maximum mortgage limits for nonoccupant owners of HUD-insured condominium units. This amendment is promulgated to conform HUD regulations to the National Housing Act,

as amended by the Housing and Urban-Rural Recovery Act of 1983.

EFFECTIVE DATE: March 29, 1985.

FOR FURTHER INFORMATION CONTACT: Brian Chappelle, Acting Director, Single Family Development Division, Department of Housing and Urban Development, Room 9270, 451 Seventh Street, SW., Washington, D.C. 20410. Telephone (202) 755-6720. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The National Housing Act (NHA) (12 U.S.C. 1701-1749) authorizes HUD/Federal Housing Administration (FHA) to insure mortgage for single family residences, including one-family units in condominiums [see section 234 of the NHA].

HUD/FHA insures lenders against losses on insured home mortgages, thereby lowering lenders' risk and encouraging a flow of credit for homeownership. The Department's insurance program has increased the opportunity for homeownership—one of the fundamental objectives of the Department. The limits on how much the Department may insure are set by the National Housing Act. Maximum mortgage amounts depend on whether the buyer intends to live in the home, the appraised value of the property, the number of family units in the dwelling and the prevailing housing prices in the area. The insured mortgage amount cannot exceed a fixed percentage of the appraised value, called the loan-to-value ratio.

Section 425 of the Housing and Urban-Rural Recovery Act of 1983 (1983 Act) amended the NHA to increase the maximum insurable amount of a mortgage on a dwelling owned by a nonoccupant mortgagor. Today's final rule implements section 425 for condominiums. HUD implemented this provision for single family residences in a final rule published on March 30, 1984 (see 49 FR 12693, 12696), but did not include amendments implementing section 425 of the 1983 Act for condominium units in that rule.

The Department is issuing today's rule as a final rule. As a matter of policy, the Department submits most of its rulemakings for public comment, either before or after effectiveness of the action. In this instance, however, the Secretary has determined that good cause exists for publishing this document as a final rule without public comment. The Department believes that prior public comment is unnecessary, because the revision to the Department's regulation grants a benefit to a class of