immobilization of glucose isomerase enzyme preparations is safe. Therefore, FDA is amending the secondary direct food additive regulations to provide for the use of glutaraldehyde and DEAE-cellulose as set forth below.

In accordance with § 170.35(c)(2) (21 CFR 170.35(c)(2)), the petitions and the documents that FDA considered and relied upon in reaching its decision to approve the use of these secondary direct food additives are on public display and available for inspection at the dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. The petitions and documents may also be inspected at the Bureau of Foods (address above) by appointment with the information contact person listed above.

FDA has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement therefore will not be prepared. The agency's findings of no significant impact and the evidence supporting this finding, contained in an environmental assessment (pursuant to 21 CFR 25.31, proposed December 11, 1979; 44 FR 71742) may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Food processing aids.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 173 is amended by adding new § 173.357, to read as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

§ 173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

Fixing agents may be safely used in the immobilization of enzyme preparations in accordance with the following conditions:

(a) The materials consist of one or more of the following:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	Limitations
Diethylaminoethyl-cellulose.	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
Glutaraldehyde	Do.

(b) The fixed enzyme preparation is washed to remove residues of the fixing materials.

Any person who will be adversely affected by the foregoing regulation may at any time on or before March 10, 1983 submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a descripton and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket numbers found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective February 8, 1983.

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

Dated: January 19, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-3214 Filed 2-7-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 182 and 184

[Docket Nos. 76G-0073, 76G-0445, 77G-0049, 77G-0099, 81G-0048, and 82G-0148]

Substances Generally Recognized as Safe; High Fructose Corn Syrup and Insoluble Glucose Isomerase Enzyme Preparations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is listing high fructose corn syrup as generally recognized as safe (GRAS) for use in food in Part 182 (21 CFR Part 182). In addition, the agency is affirming that certain insoluble glucose isomerase enzyme preparations are GRAS for use in the manufacture of high fructose corn syrup. Elsewhere in this issue of the **Federal Register**, the agency is also approving the secondary direct food additive use of diethylaminoethylcellulose (DEAE-cellulose) and glutaraldehyde as fixing agents in the immobilization of glucose isomerase enzyme preparations. FDA is taking these actions in response to GRAS petitions submitted by Standard Brands, Anheuser-Busch, Miles Laboratories, CPC International, Novo Laboratories, and GB Fermentation Industries.

DATES: Effective February 8, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1372 effective February 8, 1983.

FOR FURTHER INFORMATION CONTACT: Mary C. Custer, Bureau of Foods (HFF-335, Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: Under the procedures described in § 170.35 (21 CFR 170.35), Standard Brands, Inc., 625 Madison Ave., New York, NY 10022; Anheuser-Busch, Inc., St. Louis, MO 63118; Miles Laboratories, Inc., Elkhart, IN 46514; CPC International, Inc., International Plaza, Englewood Cliffs, NJ 07632; Novo Laboratories, Inc., 59 Danbury Rd., Wilton, CT 06897; and GB Fermentation Industries, Inc., One North Broadway, Des Plaines, IL 60016, submitted GRAS petitions (GRASP) 4G0042 (Docket No. 82G-0148), 6G0060 (Docket No. 76G-0073), 7G0080 (Docket No. 76G-0445), 7G0084 (Docket No. 77G-0049), 7G0086 (Docket No. 77G-0099), and 1G0271 (Docket No. 81G-0048), respectively. Each of the petitions requested affirmation that a specific glucose isomerase enzyme preparation, derived from a specific microorganism and rendered insoluble (fixed) with specific materials, is GRAS for use in the production of high fructose corn syrup from corn syrup glucose. The microorganisms named in the petitions are *Streptomyces rubiginosus* (GRASP 4G0042), *Actinoplanes missouriensis* (GRASP 6G0060 and 1G0271), *Streptomyces olivaceus* (GRASP 7G0080), *Streptomyces*

olivochromogenes (GRASP 7G0084), and *Bacillus coagulans* (GRASP 7G0086). Materials that are used to render the glucose isomerase enzyme preparations insoluble include DEAE—cellulose (GRASP 7G0042), diatomaceous earth (GRASP 6G0060), glutaraldehyde (GRASP 7G0080 and 7G0086), a porous ceramic carrier (GRASP 7G0084), and a combination of gelatin and glutraldehyde (GRASP) 1G0271). In addition, GRAS petitions 6G0060, 7G0084, 7G0086, and 1G0271 requested affirmation that the high fructose corn syrup produced by the specific enzyme preparation named in the petition is GRAS. FDA published notices of filing for these petitions in the **Federal Register** of August 6, 1974 (39 FR 28310), April 29, 1976 (41 FR 17953), December 7, 1976 (41 FR 53545), June 3, 1977 (42 FR 28601), May 27, 1977 (42 FR 27298), and March 10, 1981 (46 FR 15953), respectively. The agency gave interested persons an opportunity to review the petitions and to submit comments to the Dockets Management Branch. One comment, discussed elsewhere in this preamble, was submitted in response to the notice published on August 6, 1974.

High fructose corn syrup is a mixture of sugars, including approximately 52 percent glucose (dextrose), 43 percent fructose, and 5 percent maltose, isomaltose, and other sugars that are natural components of corn syrup. It is made from high dextrose equivalent corn syrup by the action of a glucose isomerase enzyme preparation.

High fructose corn syrup has been commercially produced in the United States since 1967. The major markets for high fructose corn syrup are, in descending order: beverages, baked goods, processed foods, and dairy products. According to industry reports, 4.3 billion pounds of high fructose corn syrup were produced in 1980. U.S. Department of Agriculture (USDA) production figures show that high fructose corn syrup represented 14.6 percent of the total consumption of nutritive sweeteners in 1980.

In its review of the six subject petitions, FDA has considered three major factors: (1) The source of the glucose isomerase enzyme; (2) the production, fixation, and any additional immobilization of the enzyme preparation; and (3) residual levels of processing materials that may occur in the high fructose corn syrup.

1. *Source of Glucose Isomerase Enzyme.* The subject petitions request GRAS affirmation for specific enzyme preparations derived from *S. rubiginosus, A. missouriensis, S. olivaceus, S. olivochromogenes,* and *B. coagulans.* The petitions provide precise taxonomic classification of the five microbial sources and provide information that these microbial species are well known to the scientific community and are generally available to that community. FDA has reviewed the published scientific literature and found that it contains studies utilizing these organisms, with no reported toxicity or pathogenicity associated with their use.

Extensive scientific literature searches reported by the petitioners disclosed no evidence that the organisms are toxicogenic or pathogenic. Unpublished pathogenicity studies on the particular strains of the organisms covered by the petitions, which show that these organisms are neither pathogenic nor toxicogenic to several species of laboratory animals, corroborate the safety of these organisms. The petitions provide data that show that these microorganisms can be maintained as pure cultures under conditions that minimize genetic changes. The petitions also provide information that demonstrates that appropriate microbiological, chemical, and physical controls can be maintained during the pure culture fermentation of the microorganisms, and that no antibiotics are produced by the microorganisms during the fermentation.

2. *Production, Fixation, and Additional Immobilization of Enzyme Preparation.* Each petition describes the method used to produce and to immobilize the enzyme-containing cellular materials. This information establishes the identity of processing materials and contaminants that could enter the final food product.

In the case of *S. rubiginosus* and *S. olivochromogenes*, the cells are disrupted, and a cell-free extract is prepared. The enzyme-containing extract is then fixed, that is, rendered insoluble, by adsorbing it onto DEAE-cellulose (*S. rubiginosus*) or a porous ceramic carrier (*S. olivochromogenes*). In the case of *S. olivaceus* and *B. coagulans*, intact, nonviable cells that contain glucose isomerase enzyme are simply fixed by reacting them with glutaraldehyde. In the case of *A. missouriensis*, intact, nonviable cells that contain enzyme activity are directly adsorbed onto diatomaceous earth or mixed with gelatin and reacted with glutaraldehyde.

In all the methods presented in the petitions, except those presented in GRASP 6G0060 and 7G0084, the fixed enzyme preparation is further immobilized by mechanical deposition onto a filter that is supported in a cylindrical reactor tank (column). In GRASP 7G0084, a similar result is achieved by directly depositing the enzyme-containing material onto a porous ceramic carrier, which is placed into a reactor column. In GRASP 6G0060, the enzyme material is adsorbed onto diatomaceous earth and is not further immobilized before use.

3. *Residual Levels of Processing Materials.* Each petition contains general manufacturing information that provides a basis upon which to determine the residual levels of processing materials that will occur in high fructose corn syrup. This information indicates that, under the presented methods, only very small amounts of materials from the enzyme conversion process will enter the product. Under normal conditions, the fixed enzyme preparation is extensively washed before use to remove processing materials. Furthermore, relatively small amounts of the washed enzyme preparation are used to catalyze the conversion of large quantities of glucose syrup. For example, in a continuous flow process (GRASP 4G0042, 7G0080, 7G0084, 7G0086, and 1G0271), about 7,000 to 9,000 liters of fixed enzyme preparation typically produce from 32 to 36 million liters of high fructose corn syrup. Thus, if any substances from the washed enzyme preparation do enter the high fructose corn syrup, they are diluted by a factor of at least 4,000. In a batch process (GRASP 6G0060), the ratio of syrup produced to fixed enzyme used is not as large but comparably low residual levels of processing materials are assured because the enzyme preparation is removed from the converted glucose syrup by repeated filtration. In addition, high fructose corn syrup produced by either a continuous flow or batch process is subsequently refined by ion-exchange and carbon filtration to further remove residues of the processing materials.

All of the petitions provide analytical data on the levels of processing materials present in high fructose corn syrup. These data confirm that only very small amounts of materials from the enzyme conversion process enter the high fructose corn syrup. The petitions also contain unpublished animal feeding studies establishing that residue levels of fixing agents and substances from the microbial sources up to the measured level, or the level of detection of the analytical method, are safe for human consumption. Each petition includes at least one subchronic (90-day or 6-month) study in the rat and either a 90-day or 6-month study in the dog. Other studies in the petitions include teratology studies in the rabbit or rat, reproduction/teratology studies in the rat, or

multigeneration reproduction studies in the rat.

The petitions also include specifications with supporting analytical data that indicate that the enzyme preparations, produced and fixed as indicated above, meet the general requirements and specifications for enzyme preparations set forth in the Food Chemicals Codex, 3d Ed.

In response to the notice of filing of GRASP 4G0042, published in the **Federal Register** on August 6, 1974, the agency received a comment from a law firm stating that glucose isomerase enzyme, from whatever source derived, possesses the same basic physical and chemical properties and activity. The comment suggested that GRAS status should not be confined to the use of the enzyme prepared from the particular source named by the petitioner, but rather that the use of glucose isomerase enzyme, as such, in the manufacture of high fructose corn syrup should be affirmed as GRAS.

The agency does not agree with this comment. Although the agency acknowledges that, by definition, a glucose isomerase enzyme from any source will convert glucose to fructose, the agency concludes that this fact alone is inadequate to establish the safety of the use of the final enzyme preparation. As indicated by the data provided in these petitions, an assessment of the safety and suitability of a glucose isomerase enzyme preparation must include consideration of the safety of the organism from which the enzyme preparation is derived, as well as consideration of the safety of the enzyme preparation itself, including such factors as the presence of additional cellular material and residual processing materials in the enzyme preparation and the level of enzyme preparation in the final food product.

After evaluating the petitions, the agency has made the following conclusions:

1. Data from the petitions establish that insoluble glucose isomerase enzyme preparations have no history of common use in food in the United States before January 1, 1958. Consequently, these enzyme preparations are not GRAS based on history of common use in food.

However, after evaluating the petitions, the agency concludes that insoluble glucose isomerase enzyme preparations derived from safe and suitable microorganisms, such as *S. rubiginosus, A. missouriensis, S. olivaceus, S. olivochromogenes,* and *B. coagulans,* and rendered insoluble (fixed) with GRAS ingredients or approved materials, are GRAS for use in the manfacture of high fructose corn syrup based on scientific procedures. The published scientific literature demonstrates that the microbial sources are well known and available to the scientific community and contains no reports of toxicity or pathogenicity problems associated with their use. In addition, the animal feeding studies contained in one of the petitions were presented at annual conferences of the American Association of Cereal Chemists (1971) and the American Chemical Society (1973). In addition, a substantial amount of manufacturing data for glucose isomerase enzyme preparations has been published in several publications and also was presented at the annual meetings mentioned above. The manufacturing data indicate that the use of immobilized enzyme preparations results in virtually nil levels of enzymatic processing materials entering the final food product. The conclusion that these preparations are CRAS is corroborated by analytical data and unpublished animal studies contained in the petitions that confirm the safety of the use of these enzyme preparations and the safety of the organisms from which they are derived.

The agency has further concluded that insoluble glucose isomerase enzyme preparations derived from microorganisms other than those listed above may also be GRAS, provided that the selection of the microorganism adheres to the criteria established during this review and reflected above in the discussion entitled, *"Source of Glucose Isomerase Enzyme."* Under these criteria, GRAS status is limited to enzyme preparations that are derived from microorganisms that are precisely classified, nonpathogenic, nontoxicogenic, and generally available to the scientific community. Furthermore, the published scientific literature should contain studies in which these microorganisms were utilized without any evidence of pathogenicity of toxicogenicity being associated with their use.

2. FDA currently considers the use of food-grade gelatin and diatomaceous earth in the production of high fructose corn syrup to be GRAS. A 1963 FDA advisory opinion letter concluded that diatomaceous earth of a suitable purity is GRAS for use as a filtering aid. The use of diatomaceous earth as a fixing agent for enzymes is very similar to its use as a filtering aid. FDA would classify both of these uses as processing aids as defined in § 170.3(o)(24) (21 CFR 170.3(o)(24)), and both uses would result in the same level of contact with food. Finally, in both of these uses, the diatomaceous earth is removed from the final food product. Therefore, the agency considers the use of diatomaceous earth as a fixing agent for enzymes to be GRAS. The agency intends to publish a proposal addressing the GRAS status of the food use of diatomaceous earth, including its use as a fixing agent for enzymes, in the near future.

The agency has traditionally considered materials such as ceramics, glass, and stainless steel as GRAS for food-contact use, based on their safe history of common use as food-contact materials before 1958. However, because the use of these materials has been so widespread, the agency has never considered it necessary to list these materials as GRAS. Therefore, the agency is noting that the use of these materials in the production of high fructose corn syrup is GRAS but is continuing its traditional practice of not specifically listing them as GRAS.

3. Glutaraldehyde and DEAE-cellulose, when used in the immobilization of glucose isomerase enzyme preparations, although not GRAS, are safe secondary direct food additives under section 409 of the Federal Food, Drug, and Cosmetic Act. There is no evidence that these substances were commonly used in food for these purposes in the United States before 1958. In addition, the agency has determined that the potential toxicity of crosslinking agents, including glutaraldehyde, and resins, including DEAE-cellulose, that could be used to fix glucose isomerase enzyme preparations establishes a basis for assuring limited consumer exposure to these substances. Consequently, the agency has concluded that the most appropriate way of regulating this group of substances and of ensuring their continued safe use in food is to provide for the use of fixing agents in a food additive regulation.

4. High fructose corn syrup as defined below in new § 182.1866 (21 CFR 182.1866) is GRAS for use in food. The agency has concluded that high fructose corn syrup is as safe for use in food as sucrose, corn sugar, corn syrup, and invert sugar. FDA bases this conclusion on the saccharide composition of this product and the safety of the insoluble glucose isomerase enzyme preparations used in its manufacture. High fructose corn syrup contains approximately the same glucose to fructose ratio as honey, invert sugar, and the disaccharide sucrose. In addition, the minor saccharides contained in high fructose corn syrup are the same, and present at similar levels, as the nonglucose saccharides that are present in corn syrup and corn sugar. Sucrose is

currently GRAS for use in food under § 182.1(a) (21 CFR 182.1(a)) and sucrose, corn sugar (sirup), and invert sugar are listed in § 182.90 (21 CFR 182.90) as GRAS substances that migrate from food packaging. In addition, the agency has historically considered sucrose, corn sugar, corn syrup, and invert sugar to be GRAS for direct use in food.

As a result of these conclusions, the agency is taking the following actions:

1. The agency is approving the secondary direct food additive use of DEAE-cellulose and glutaraldehyde as fixing agents in the immobilization of glucose isomerase enzyme preparations. A document amending Part 173 (21 CFR Part 173) to provide for this use of these subtances is published elsewhere in this issue of the **Federal Register**.

2. The agency is affirming under Part 184 (21 CFR Part 184) the GRAS status of certain insoluble (fixed) glucose isomerase enzyme preparations, derived from safe and suitable microorganisms, including *S. rubiginosus, A. missouriensis, S. olivaceus, S. olivochromogenes,* and *B. coagulans*, for use in the manufacture of high fructose corn syrup. These enzyme preparations may be fixed with GRAS ingredients and, if further immobilized, may also be fixed with materials approved under Part 173. The agency has determined that separate GRAS affirmation regulations for specific enzyme preparations are not necessary. As shown in the petitions, insoluble glucose isomerase enzyme preparations, derived from safe and suitable sources and fixed with either GRAS or approved materials, result in a product that is safe and suitable for use in food. Separate regulations for individual enzyme preparations would merely introduce an element of rigidity that is not necessary to ensure the safety of the product, into a relatively new manufacturing process that is undergoing considerable change in response to technological advances.

3. The agency is listing in Part 182 (21 CFR Part 182) high fructose corn syrup as GRAS for use in food. As indicated above, the agency considers that this product is as safe as sucrose, corn sugar, corn syrup, and invert sugar for use in food. The agency currently considers these ingredients as GRAS for use in food under the provisions of Part 182. Therefore, the agency is listing high fructose corn syrup in Part 182.

The agency has undertaken, although it has not yet completed, general GRAS safety reviews of sucrose (47 FR 53923; November 30, 1982) and of corn sugar, corn syrup, and invert sugar (47 FR 53917; November 30, 1982). These safety reviews not only address the safety of glucose and fructose as food ingredients but also evaluate the effects of total sugar consumption in the diet. Because of the similarity of high fructose corn syrup to these ingredients, FDA will consider whether to affirm its GRAS status following the completion of the general safety reviews of sucrose and of corn syrup, corn sugar, and invert sugar.

The agency is not specifying levels of use or food categories in the GRAS regulations for high fructose corn syrup and for insoluble glucose isomerase enzyme preparations. High fructose corn syrup is listed in Part 182 for use as a nutritive sweetener in food. Its use in food and its listing as GRAS are based on its similarity to sucrose, corn sugar, corn syrup, and invert sugar. These ingredients have widespread use in food, and their current GRAS approval contains no specific conditions of use. Therefore, the agency concludes that it is impractical and inappropriate to list food categories and levels of use for this ingredient. Insoluble glucose insomerase enzyme preparations are used in the manufacture of one product—high fructose corn syrup. Consequently, in lieu of food categories, the regulation specifies this use. Furthermore, the insoluble enzyme preparation is present at such small levels in high fructose corn syrup that the agency has concluded that it is neither useful nor practical to list its levels of use in food. Therefore, the agency is affirming the GRAS status of the insoluble glucose insomerase enzyme preparation when it is used under current good manufacturing practice conditions of use in accordance with § 184.1(b)(1) (21 CFR 184.1(b)(1)). To make clear, however, that the affirmation of the GRAS status of this substance is based on an evaluation of currently known uses, the regulation sets forth the technical effect that FDA evaluated.

In the **Federal Register** of September 7, 1982 (47 FR 39199), FDA proposed to adopt a general policy restricting the circumstances in which it will specifically describe conditions of use in regulations affirming substances as GRAS under 21 CFR 184.1(b)(1) or 186.1(b)(1). The agency proposed to amend its regulations to indicate clearly that it will specify one or more of the current good manufacturing practice conditions of use in regulations for substances affirmed as GRAS with no limitations other than current good manufacturing practice only when the agency determines that it is appropriate to do so.

The format of the final regulation is different from that in previous GRAS affirmation regulations. FDA has modified paragraph (c) of § 184.1372 to make clear the agency's determination that GRAS affirmation is based upon current good manufacturing practice conditions of use, including the technical effect listed, this change has no substantive effect but is made merely for clarity.

The agency has determined under 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. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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 the Order. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch (address above).

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) good 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), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. Part 182 is amended by adding new § 182.1866, to read as follows:

§ 182.1866 High fructose corn syrup.

(a) *Product.* High fructose corn syrup is a sweet, nutritive saccharide mixture containing approximately 52 percent (dry weight) glucose, 43 percent (dry weight) fructose, and 5 percent (dry weight) other saccharides. It is prepared as a clear aqueous solution from high dextrose equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to

fructose utilizing an insoluble glucose isomerase enzyme preparation described in § 184.1372 of this chapter.

(b) *Limitations, restrictions, or explanations.* This substance is generally recognized as safe when used in food as a nutritive carbohydrate sweetener at levels not to exceed current good manufacturing practice.

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

2. Part 184 is amended by adding new § 184.1372, to read as follows:

§ 184.1372 Insoluble glucose isomerase enzyme preparations.

(a) Insoluble glucose isomerase enzyme preparations are used in the production of high fructose corn syrup described in § 182.1866 of this chapter. They are derived from recognized species of precisely classified, nonpathogenic, and nontoxicogenic microorganisms, including *Streptomyces rubiginosus, Actinoplanes missouriensis, Streptomyces olivaceus, Streptomyces olivochromogenes,* and *Bacillus coagulans,* that have been grown in a pure culture fermentation that produces no antibiotics. They are fixed (rendered insoluble) for batch production with GRAS ingredients or may be fixed for further immobilization with either GRAS ingredients or materials approved under § 173.357 of this chapter.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d Ed. (1981), p. 107, 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 (GRAS) 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 glucose to fructose.

(2) The ingredient is used in high fructose corn syrup, at levels not to exceed current good manufacturing practice.

Effective date. This regulation shall become effective February 8, 1983.

(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: January 19, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-3215 Filed 2-7-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Ch. I

National Motor Carrier Advisory Committee

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of public meetings.

SUMMARY: The FHWA announces that the National Motor Carrier Advisory Committee will hold a series of public meetings in San Francisco, California; Chicago, Illinois; and Washington, D.C., to solicit comments concerning the statement of FHWA interpretation and policy addressing the truck size and weight provisions contained in the Surface Transportation Assistance Act of 1982 (STAA) and the DOT Appropriations Act of 1982. The FHWA statement was issued in February 1, 1983, and published in the **Federal Register** on February 3, 1983 (48 FR 5210).

DATES: The meetings will be held beginning at 9:00 a.m. on February 24, 1983 in Washington, D.C., on March 2, 1983 in Chicago, Ill.; on March 10, 1983 in San Francisco, Calif.

ADDRESSES: The meetings will be held at the following places:

February 24, 1983 in Washington, D.C., at the Department of Transportation's Headquarters Building, 400 Seventh Street, SW., Room 2230.

March 2, 1983 in Chicago, Illinois, at the Federal Building, 230 S. Dearborn Street, Room 349.

March 10, 1983 in San Francisco, California, at the Federal Building, 450 Golden Gate Avenue, Room 200.

FOR FURTHER INFORMATION CONTACT: Mr. James J. Stapleton, Acting Executive Director, National Motor Carrier Advisory Committee, Federal Highway Administration, HCC-20, Room 4224, 400 Seventh Street, SW., Washington, D.C. 20590, (202) 426-0834. Office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

SUPPLEMENTARY INFORMATION: 1. *Agenda.* The agenda of the meetings will be limited to the receipt of comments concerning the statement of FHWA interpretation and policy addressing the truck size and weight provisions contained in the STAA and the DOT Appropriations Act of 1982. The FHWA statement addressed the explicit truck weight, length and width statutory provisions and the following primary issues relating to those provisions:

(a) Effective dates;

(b) Identification of the "qualifying highways" referred to in Sections 411 of the STAA and 321 of the DOT Appropriations Act; and

(c) Definition of "reasonable access" referred to in Sections 133 and 412 of the STAA.

2. *Submission of comments and request to testify.* Interested persons are invited to comment on the subject-matter of the meetings. Written comments may be submitted at the time and place of the meetings. (These comments are in addition to any comments that anyone may wish to submit in response to the request for comments in connection with the FHWA policy statement published in the **Federal Register** on February 3, 1983.

Anyone desiring an opportunity to make an oral presentation at one of the meetings should make a written request to do so at least ten days prior to the date of the meeting in question. The person making the request should describe his or her interest and, if appropriate, state whether he or she is a representative of a group or class of persons that has such an interest. A telephone number should be given where he or she may be contacted up until the day before the meeting. Requests to testify should be addressed to: Mr. James J. Stapleton, Acting Executive Director, National Motor Carrier Advisory Committee, Federal Highway Administration, HCC-20, Room 4224, 400 Seventh Street, SW., Washington, D.C. 20590.

3. *Conduct of Meetings.* The Advisory Committee reserves the right to limit the number of speakers from any one group or organization to be heard at the meetings, to schedule their respective presentations, and to establish the procedures governing the conduct of the meetings. The length of each presentation may be limited, based on the number of persons or organizations requesting to be heard.

A member of the Advisory Committee will be designated to preside at the meetings, which will not be judicial or evidentiary-type hearings. Questions may be asked only by members of the Advisory Committee or the Acting Executive Director, and there will be no cross examination of persons presenting statements.

Any person attending and who wishes to ask a question may submit the

question in writing to the presiding officer.

Any further procedural rules needed for the proper conduct of the meetings will be announced by the presiding officer.

Issued on: February 4, 1983.

R. A. Barnhart,

Federal Highway Administrator, Federal Highway Administration.

[FR Doc. 83-3471 Filed 2-7-83; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 885

[Docket No. R-83-1058]

Loans for Housing for the Elderly or Handicapped; Fiscal Year 1983 Interest Rate

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

ACTION: Final rule.

SUMMARY: In compliance with the Further Continuing Appropriations Act, 1983 (Pub. L. 97-377), this rule amends 24 CFR Part 885 to establish the interest rate for direct loans for housing for the elderly or handicapped made during Fiscal Year 1983 at 9¼ percent per annum. This interest rate is the same rate as was applicable to loans made during Fiscal Year 1982.

EFFECTIVE DATE: February 8, 1983.

FOR FURTHER INFORMATION CONTACT: Robert W. Wilden, Director, Elderly, Cooperative, Congregate and Health Facilities Division, 451 7th Street, SW., Room 6138, Washington, D.C. 20410, Telephone (202) 426-8730. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Section 202(a)(3) of the Housing Act of 1959, as amended, provides that a loan for housing for the elderly or handicapped shall bear interest at a rate which is not more than a rate determined by the Secretary of the Treasury, taking into consideration the average interest rate on all interest bearing obligations of the United States then forming a part of the public debt computed at the end of the fiscal year next preceding the date on which the loan is made, adjusted to the nearest one-eighth of one percent, plus an allowance adequate in the judgment of the Secretary of HUD to cover administrative costs and probable losses under the program. The existing regulation provision (24 CFR 885.410(g)) incorporates a determination by the Secretary that the allowance for administrative costs and probable losses should be one-fourth of one percent (.25%) per annum for both the construction and permanent loan periods.

Application of this formula to loans made during Fiscal Year 1983 would have yielded an interest rate of 11⅞ percent per annum. The Further Continuing Appropriations Act, 1983, however, establishes a 9¼ percent per annum interest rate for direct loans made in Fiscal Year 1983.

Since this amendment implements a statutory mandate the Secretary has determined that notice and public procedure on this amendment are unnecessary. In addition the Secretary has determined that it is in the public interest to implement his decision as soon as possible, so that projects previously approved as feasible under the Fiscal Year 1982 interest rate can proceed to construction without delay. Accordingly, good cause exists for publishing this amendment as a final rule, without providing a prior comment period, and for making it effective less than 30 days after such publication.

Section 7(o)(3) of the Department of HUD Act (42 U.S.C. 3535(o)(3)) provides for a delay in the effectiveness of HUD regulations for a period of 30 calendar days of continuous session of Congress after publication, unless waived by the Chairmen and Ranking Minority Members of the Senate Committee on Banking, Housing and Urban Affairs and the House Committee on Banking, Finance and Urban Affairs. The Secretary has requested and received such waivers.

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50, which implement Section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection and copying during regular business hours at the Office of the Rules Docket Clerk, Office of the General Counsel, Room 10278, Department of Housing and Urban Development, 451 Seventh Street S.W., Washington, D.C.

This rule does not constitute a "major rule" as that term is defined in Section 1(b) of Executive Order 12291 on Federal Regulation. Analysis of the rule indicates that it does not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Pursuant to Section 605(b) the (Regulatory Flexibility Act), the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities because, under the rule, the current interest rate would remain in effect.

The Catalog of Federal Domestic Assistance Program title and number is Housing for the Elderly or Handicapped, 14.157.

This rule was not listed in the Department's Semiannual Agenda of Regulations published pursuant to Executive Order 12291 and the Regulatory Flexibility Act of October 28, 1982 (47 FR 48422).

List of Subjects in 24 CFR Part 885

Aged, Grant programs—housing and community development, Handicapped, Loan programs—housing and community development, Low and moderate income housing.

PART 885—LOANS FOR HOUSING FOR THE ELDERLY OR HANDICAPPED

Accordingly, 24 CFR 885.410(g) is revised to read as follows:

§ 885.410 Amount and terms of financing.

* * * * *

(g) Except for loans made during Fiscal Years 1982 and 1983, which shall bear an interest rate of nine and one-fourth percent (9¼) per annum, loans shall bear interest at a rate established by the Secretary by adding:

(1) A rate determined by the Secretary of the Treasury to be the average interest rate on all interest-bearing obligations of the United States then forming a part of the public debt computed at the end of the fiscal year immediately prior to the date on which the loan is made; plus (2) an allowance to cover administrative costs and probable losses under the program, which allowance has been determined