(3) The claim may indicate that oral hygiene and proper dental care may help to reduce the risk of dental disease.

(4) The claim may indicate that the sugar alcohol serves as a sweetener.

(e) *Model health claim*. The following model health claims may be used in food labeling to describe the relationship between sugar alcohol-containing foods and dental caries.

(1) Example of the full claim:

(i) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.

(ii) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.

(2) Example of the shortened claim for small packages:

(i) Does not promote tooth decay.

(ii) May reduce the risk of tooth decay.

Dated: August 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–21481 Filed 8–20–96; 8:53 am]

BILLING CODE 4160–01–F

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21 CFR Parts 182 and 184

[Docket No. 85N–0548]

Direct Food Substances Affirmed as Generally Recognized as Safe; High Fructose Corn Syrup

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for substances that are generally recognized as safe (GRAS) to affirm that high fructose corn syrup (HFCS), prepared from high dextrose equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose utilizing one of several glucose isomerase enzyme preparations, is GRAS as a direct human food ingredient. This action is in response to six petitions filed by members of the food industry.

DATES: Effective August 23, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 184.1866, effective August 23, 1996.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3078.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 8, 1983 (48 FR 5716), FDA published a document that listed HFCS as GRAS for use in food (§ 182.1866 (21 CFR 182.1866)) and also affirmed that certain insoluble glucose isomerase enzyme preparations are GRAS for use in the manufacture of HFCS (§ 184.1372 (21 CFR 184.1372)) (hereinafter referred to as the 1983 final rule). The agency published this final rule in response to six industry petitions that requested GRAS affirmation for certain insoluble glucose isomerase enzyme preparations used to make HFCS and for the manufactured product itself.

The basis for listing HFCS in 21 CFR part 182 was that HFCS is made with enzyme preparations that FDA has affirmed as GRAS; the saccharide composition (glucose to fructose ratio) of HFCS is approximately the same as that of honey, invert sugar, and the disaccharide sucrose; and the minor components (primarily higher saccharides of glucose) of HFCS are also found at similar levels in corn syrup and corn sugar which are already on the GRAS list. Therefore, FDA concluded that it was appropriate to list HFCS as GRAS for use in food while the agency fully evaluated it during the comprehensive safety review of corn sugar, corn syrup, invert sugar, and sucrose.

In the 1983 final rule, the agency gave notice to all interested parties that when the agency completed its comprehensive safety review of corn sugar (dextrose), corn syrup, invert sugar, and sucrose, it would examine the data on these substances to determine whether those data provide an adequate basis to affirm that HFCS is GRAS. In the Federal Register of November 7, 1988 (53 FR 44862), the agency published a final rule affirming that the use of corn sugar, corn syrup, invert sugar, and sucrose in food is GRAS.

II. The Safety Review of High Fructose Corn Syrup

In the Federal Register of November 7, 1988 (53 FR 44904), FDA proposed to affirm that the use of HFCS in food is GRAS (hereinafter referred to as the 1988 HFCS proposal). Included in the 1988 HFCS proposal was the agency's: (1) Evaluation of the data contained in the petitions and of their relationship to the safety of HFCS; (2) discussion of the relevancy of reports by the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology entitled ''Evaluation of the Health Aspects of Corn Sugar (Dextrose), Corn Syrup, and Invert Sugar as Food Ingredients'' (Ref. 1) and ''Evaluation of the Health Aspects of Sucrose as a Food Ingredient'' (Ref. 2) to the safety assessment of HFCS; and (3) discussion of the relevancy of FDA's Sugars Task Force Report ''Evaluation of the Health Aspects of Sugars Contained in Carbohydrate Sweeteners'' (Ref. 3) to the safety evaluation of HFCS.

The agency made it clear during its safety evaluation of corn sugar, corn syrup, invert sugar, and sucrose that its exposure estimate for HFCS included exposure to HFCS containing 55 percent fructose (HFCS–55) (Ref. 3). Furthermore, FDA noted that most of the components found in HFCS

containing 43 percent fructose (HFCS–43) (approximately equimolar mixtures of glucose and fructose; residues from corn syrup; and residues from the glucose isomerase enzyme preparations) are also found in HFCS–55. Therefore, the agency noted that the safety evaluation of the major components in HFCS–43 is also applicable to HFCS–55, and it stated that it would consider including HFCS–55 in its rule affirming the GRAS status of HFCS if it received, as comments on the 1988 HFCS proposal, information on the production of HFCS–55 adequate to allow it to identify possible residues from processing materials and to ensure that the level of these residues in the final product is safe (53 FR 44904 at 44907).

The 1988 HFCS proposal did not include 90 percent fructose (HFCS–90); however, HFCS–90 is also a commercially available product. This product contains a substantially different ratio of glucose to fructose than either HFCS–43 or HFCS–55. The HFCS–90 is not included in this rulemaking because the agency does not have adequate information to assess the safety of residual levels of the processing materials in the final product. Moreover, FDA did not include HFCS–90 in the agency's exposure estimate for HFCS, even though the agency was aware of minor uses of HFCS–90 as an ingredient in low-calorie foods. Finally, FDA's report on its safety review of the sugars contained in carbohydrate sweeteners did not include HFCS–90 primarily because HFCS–90 does not contain approximately equimolar amounts of glucose and fructose (53 FR 44904 at 44907). Thus, additional data on the effects of fructose consumption that is not balanced with glucose consumption would be needed to ensure that this product is safe. Because HFCS–90 has not been included in this rulemaking, consideration of the GRAS status of this substance will need to proceed through the petition process in accordance with § 170.35.

III. Comments on the 1988 HFCS Proposal

The original comment period for the 1988 HFCS proposal ended on January 6, 1989. In the Federal Register of January 27, 1989 (54 FR 4045), in response to requests from two trade associations, FDA extended the comment period until April 6, 1989, to allow sufficient time for interested persons to respond to the agency's request for information on the manufacturing process for HFCS–55. FDA received four submissions in response to the 1988 HFCS proposal, each containing one or more comments. One submission was from a diabetes research center, and the other three were from trade associations. In addition, recently a further comment was received from one of the trade associations. This comment modified some of the information that the association had submitted in its previous comment.

1. The Diabetes Research Center stated its opinion that the safety of HFCS as it relates to diabetics has not been totally established. It suggested that the fact that its safety for diabetics had not been fully established should be stated somewhere on the product label. The comment did not provide any support for its conclusion or for the suggested labeling requirement.

FDA does not agree with this comment. FDA's Sugars Task Force stated in its report (Ref. 3) that it could not find any basis in the scientific literature to conclude that there was the potential for an adverse effect in diabetics from increased fructose consumption. The comment did not present any evidence of any developments since the publication of the Task Force's report almost 10 years ago that would contradict the Task Force's finding.

In a 1994 review of Nutrition Principles for the Management of Diabetes and Related Complications (Ref. 4), sponsored by the American Diabetes Association (ADA), a national expert body for diabetes, the effects of sucrose, fructose, and other nutritive sweeteners were discussed in detail. The fructose used in the studies that were discussed in the review was primarily crystalline fructose. HFCS, which has a saccharide composition similar to sucrose, was not separately considered. The overall findings that emerged from this review (Ref. 5) were that ''scientific evidence has shown that the use of sucrose as part of the meal plan does not impair blood glucose control in individuals with type I or type II diabetes,''and that ''dietary fructose produces a smaller rise in plasma glucose than isocaloric amounts of sucrose and most starchy carbohydrates.''

Moreover, the ADA dietary guidelines for diabetics state that diabetics may consume a modest amount of sugars as long as metabolic control and desirable body weight are maintained (Ref. 5). The guidelines do not include a recommendation to avoid any specific sweetener because of safety concerns.

FDA's policy in the case of food ingredients, such as FD&C Yellow No. 5 and sulfites, to which subpopulations are allergic or sensitive is to rely on the declaration of the presence of the substance in the ingredient list, rather than to require a special statement on the label. The agency considers that declaration of the ingredient will give the sensitive subpopulation an opportunity to avoid the food. HFCS, like any other ingredient, will have to be declared on the ingredient list when used in food. Thus, even if there were a basis for a safety concern about HFCS in diabetics, FDA finds no reason why it is not adequate to treat this ingredient like other ingredients of concern to particular subpopulations.

Given the absence of any data supporting a safety concern for HFCS in diabetics, the agency finds no rational basis for requiring on products that contain this sweetener a label statement that advises that the safe use of HFCS by diabetics has not been fully established. The agency concludes that there is no evidence to suggest that HFCS is any less safe for diabetics than any other commonly used sweetener. Based on the foregoing, FDA concludes that no change in § 184.1866 in response to this comment is warranted.

2. In three submissions, three trade associations strongly endorsed affirming the use of HFCS in food as GRAS. These comments asked that the final rule recognize that the item of commerce contains 42 percent fructose (HFCS–42) on a dry weight basis, and that the reference to the 43 percent fructose dry weight product be deleted. The comments discussed in detail the manufacturing process for HFCS–55 and asked that the final rule be modified to allow manufacturers the flexibility to make HFCS–42 and HFCS–55 according to the identity and specifications described. Subsequently, one of these trade associations submitted a comment that amended its earlier submission regarding the identity and specifications for HFCS to read as follows:

''High Fructose Corn Syrup is a sweet, nutritive saccharide mixture prepared as a clear, aqueous solution from high-dextrose-equivalent corn starch hydrolysate by the partial enzymatic conversion of glucose (dextrose) to fructose, using an insoluble glucose isomerase preparation that complies with 21 CFR 184.1372 and that has been grown in a pure culture fermentation that produces no antibiotics. It is a water-white to light yellow, somewhat viscous liquid that darkens at high temperatures. It is miscible in all proportions with water. This product has the following requirements:

Assay, 42 Percent High Fructose Corn Syrup: Not less than 97.0 percent total saccharides (dry weight), of which not less than 42.0 percent consists of fructose (dry weight), not less than 92.0 percent consists of monosaccharides, and not more than 8.0 percent (dry weight) of other saccharides. 55 Percent High Fructose Corn Syrup: Not less

than 95.0 percent total saccharides (dry weight), of which not less than 55.0 percent consists of fructose (dry weight), not less than 95.0 percent consists of monosaccharides, and not more than 5.0 percent (dry weight) of other saccharides. Arsenic (as As), not more than 1 milligram per kilogram. Color, within the range specified by the vendor. Heavy metals (as Pb), not more than 5 milligrams per kilogram. Lead, not more than 0.1 milligram per kilogram. Sulfur dioxide, not more than 0.003 percent. Total solids, 42 percent high fructose corn syrup: not less than 70.5 percent. 55 Percent high fructose corn syrup: not less than 76.5 percent.''

This information is similar to that published in Food Chemicals Codex, 4th ed., p. 191 (1996), in the monograph entitled ''High-Fructose Corn Syrup.''

FDA has reviewed the comments and acknowledges that the item of commerce is HFCS–42. The agency agrees with the identity and specifications recommended by the latter comment for HFCS (HFCS–42 or HFCS–43). FDA concludes that the identity and specifications that it is adopting are adequate to ensure that the public health is protected.

The agency also has reviewed the comments from the three trade associations requesting the inclusion of HFCS–55 in the final rule. FDA notes that the comments provided detailed information on the manufacture of HFCS–55, including information on processing aids and residues of these materials in the final product. In addition, the comments provided information on the identity of, and specifications for, the HFCS–55 product.

FDA concludes that the manufacturing process for HFCS–55 does not raise any safety concerns, and that the residues of the processing materials in this product are safe, because HFCS–55 is prepared from HFCS–42 using standard techniques. In addition, as noted earlier in this final rule, the agency has determined that the safety evaluation of the major components in HFCS–42 is also applicable to HFCS–55. Thus, FDA finds that information provided by the comments is sufficient for the agency to include HFCS–55 in the final rule. Accordingly FDA has modified the final rule to include HFCS–55.

The agency has also reviewed the identity and specifications suggested for HFCS–55 in the comments. FDA concludes that the suggested identity and specifications are adequate to ensure that the public health will be protected.

In addition, the agency has determined that because the components of HFCS–55 are similar to HFCS–42, and there are no safety concerns with these components, there is no need to differentiate between these two HFCS's on product labels for consumers.

3. A comment from a trade association included a recommendation for FDA to adopt the Food Chemicals Codex (3d ed., 2d supplement) assay requirements for HFCS. The association also pointed out that the Food Chemicals Codex has published food grade specifications for HFCS.

In the 1988 HFCS proposal, the agency stated that it would cooperate with the National Academy of Sciences to establish specifications for HFCS. The 1988 HFCS proposal also stated that when acceptable specifications are developed, the agency will incorporate them into the regulation. Recently, however, as stated above, industry submitted a comment suggesting new identities and specifications for HFCS–42 and HFCS–55 that are similar to those published in the Food Chemicals Codex, 4th ed., p. 191 (1996), in the monograph entitled ''High-Fructose Corn Syrup.'' These identities and specifications, as discussed in response to comment 2 of this document, are acceptable to the agency and are therefore incorporated by reference.

IV. Conclusion

Based on the conclusions of the Federation of American Societies for Experimental Biology on the safety evaluations of corn sugar, corn syrup, invert sugar, and sucrose (Refs. 1 and 2) and of FDA's Task Force Report on the health aspects of sugars contained in carbohydrate sweeteners (Ref. 3), in the 1988 HFCS proposal, the agency proposed to affirm that the use of HFCS in food is GRAS. FDA has considered all the comments received on the 1988 HFCS proposal and has found that no information has been submitted in response to the proposal that warrants a change in FDA's tentative conclusion about the safety of HFCS or about whether it is GRAS.

The agency agrees with comments to the 1988 HFCS proposal that the item of commerce is HFCS containing not less than 42 percent fructose. Thus, FDA has included HFCS containing not less than 42 percent fructose dry weight in the description of the identity of HFCS in the final rule. In addition, FDA has incorporated by reference the other aspects of the identity and specifications for HFCS–42 that were published in the Food Chemicals Codex, 4th ed., p. 191 (1996), in the monograph entitled ''High-Fructose Corn Syrup'' and that are similar to industry comments to the 1988 HFCS proposal.

Also, sufficient information was submitted in the comments to justify affirming HFCS–55 as GRAS and to provide specifications for this substance. Therefore, the agency has included HFCS containing not less than 55 percent fructose dry weight in the description of the identity of HFCS in the final rule. In addition, FDA has incorporated by reference the other aspects of the identity and specifications for HFCS–55 that were published in the Food Chemicals Codex, 4th ed., p. 191 (1996), in the monograph entitled ''High-Fructose Corn Syrup,'' and that are similar to industry comments to the 1988 HFCS proposal. Furthermore, the agency is including a sentence in the regulation to characterize the manufacturing process that converts HFCS–42 to HFCS–55, i.e., ''The product containing more than 50 percent (dry weight) fructose may be prepared through concentration of the fructose portion of the mixture containing less than 50 percent fructose.''

Thus, FDA is including two types of HFCS in this final rule. HFCS–42 contains at least 42 percent fructose, approximately 50 percent glucose, and not more than 8 percent other saccharides. HFCS–55 contains at least 55 percent fructose, approximately 40 percent glucose, and not more than 5 percent other saccharides. HFCS–42 and HFCS–55 both contain similar saccharide compositions (glucose to fructose ratio) as honey, invert sugar, and the disaccharide sucrose, and the minor components (primarily higher saccharides of glucose) of HFCS–42 and HFCS–55 are also present at similar levels in corn syrup and corn sugar, which FDA has already found to be GRAS.

FDA has previously considered the environmental effects of this rule as announced in the 1988 HFCS proposal. FDA did not receive any information or comments that would affect the agency's determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Analysis of Impacts

FDA has examined the economic implications of the final rule affirming the GRAS status of HFCS, prepared from high dextrose-equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose utilizing one of several glucose isomerase enzyme preparations, for use as a direct human food ingredient, under Executive Order 12866 and the Regulatory Flexibility Act. Executive Order 12866 directs agencies to assess

all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act (Pub. L. 96–354) requires analyzing options for small businesses. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866.

Affirming that the use of HFCS that contains either not less than 42 percent fructose or not less than 55 percent fructose in food is GRAS will expand the formulation possibilities for food manufacturers, including small businesses. Therefore, in accordance with the Regulatory Flexibility Act, FDA has also determined that this rule will have a positive impact on small businesses.

Because no current activity is prohibited by this final rule, the compliance cost to firms is zero. Total costs are also zero because there will be no increase in the health risks faced by consumers resulting from this final rule. Potential benefits include the wider use of these substances to achieve intended technical effects and the savings that will result from not having to prepare any new petitions to affirm that the use of these substances in food is GRAS.

VI. Effective Date

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

VII. References

The following references have been placed on display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1.''Evaluation of the Health Aspects of Corn Sugar (Dextrose), Corn Syrup, and Invert Sugar as Food Ingredients'' (SCOGS–50), Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1976.

2.''Evaluation of the Health Aspects of Sucrose as a Food Ingredient'' (SCOGS–69), Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1976.

3. Glinsmann W. H., H. Irausquin, and Y. K. Park, ''Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners,'' Report of Sugars Task Force 1986, *Journal of Nutrition*, 116(11S):S1–S216, 1986.

4. Franz, M. J. et al, ''Nutrition Principles for the Management of Diabetes and Related Complications,'' *Diabetes Care*, 17:490–518, 1994.

5. American Diabetes Association, ''Nutrition Recommendations and Principles for People with Diabetes Mellitus,'' *Diabetes Care*, 17:519–522, 1994.

List of Subjects

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 182 continues to read as follow:

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

§ 182.1866 [Removed]

2. Section 182.1866 *High fructose corn syrup* is removed from subpart B.

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

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

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

4. Section 184.1372 is amended by revising paragraph (a) 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 § 184.1866. 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.

* * * * *

5. Section 184.1866 is added to subpart B to read as follows:

§ 184.1866 High fructose corn syrup.

(a) High fructose corn syrup, a sweet, nutritive saccharide mixture containing either approximately 42 or 55 percent fructose, is prepared as a clear aqueous solution from high dextrose-equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose using an insoluble glucose isomerase enzyme preparation described in § 184.1372. The product containing more than 50 percent fructose (dry weight) is prepared through concentration of the fructose portion of the mixture containing less than 50 percent fructose.

(b) The ingredient shall conform to the identity and specifications listed in the monograph entitled ''High-Fructose Corn Syrup'' in the Food Chemicals Codex, 4th ed. (1996), pp. 191–192, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

Dated: August 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–21482 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Semduramicin with Bacitracin Methylene Disalicylate and Roxarsone; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.