accordance with the provisions of the Commission's meetings policy (16 CFR Part 1012), Commission personnel shall not become involved in meetings concerning the development of voluntary standards that are not open to the public for attendance and observation. Attendance of Commission personnel at a voluntary standard meeting shall be noted in the public calendar in accordance with the Commission's meetings policy.

(d) Generally, Commission employees may become involved in the development of voluntary standards only if they are made available for comment by all interested parties prior to their use or adoption.

(e) Involvement by Commission officials and employees in voluntary standards bodies or standards-developing groups does not, of itself, connote Commission agreement with, or endorsement of, decisions reached, approved or published by such bodies or groups.

§ 1031.14 Observation criteria.

A Commission official or employee may, on occasion, attend voluntary standards meetings for the sole purpose of observation, with the advance approval of his or her supervisor and any other person designated by agency management procedures. Commission officials and employees shall notify the Voluntary Standard Coordinator, for information purposes, prior to observing a voluntary standards meeting.

§ 1032.15 Communication criteria.

(a) Commission officials and employees, who are not in the positions listed in § 1031.12(a), or who are not already authorized to communicate with a voluntary standards group or representative incidental to their approved membership in a voluntary standard organization or group or as part of their participation or monitoring of a voluntary standard, may:

(1) Communicate, within the scope of their duties, with a voluntary standard group or representative on voluntary standards matters which are substantive in nature, i.e., matters that pertain to the formulation of the technical aspects of a specific voluntary standard or the course of conduct for developing the standard, only with the specific advance approval from the person or persons to whom they apply to obtain approval for participation or monitoring pursuant to § 1031.13. The approval may indicate the duration of the approval and any other conditions.

(2) Communicate, within the scope of their duties, with a voluntary standards group or representative concerning voluntary standards activities which are not substantive in nature.

(b) Commission employees may communicate with voluntary standards organizations only in accordance with Commission procedures designed to assure staff review and consensus.

(c) Commissioners can engage in substantive and non-substantive written communications with voluntary standards bodies or representatives, provided a disclaimer in such communications indicates that any substantive views expressed are only their individual views and are not necessarily those of the Commission. Where a previous official Commission vote has taken place, that vote should also be noted in any such communication. Copies of such communications shall thereafter be provided to the other Commissioners, the Office of the Secretary, and the Voluntary Standards Coordinator.

(d) The Voluntary Standards Coordinator shall be furnished a copy of each written communication of a substantive nature and a report of each oral communication of a substantive nature between a Commission official or employee and a voluntary standards organization or representative which pertains to a voluntary standards activity. The information shall be provided to the Voluntary Standards Coordinator as soon as practicable after the communication has taken place.

Date: October 31, 1988.

Sadye E. Dunn,

Secretary.

[FR Doc. 88-25574 Filed 11-4-88; 8:45 am]

BILLING CODE 6355-01-M

INTERNATIONAL TRADE COMMISSION

19 CFR Part 210

Conduct of Complainants Prior to the Institution of Investigations of Unfair Practices in Import Trade; Articulation of Duty of Candor, Procedures for Alleging a Violation of Duty, and Sanctions for Violations

AGENCY: U.S. International Trade Commission.

AGENCY: Notice of proposed rulemaking.

SUMMARY: The proposed rules would amend the Commission's *Rules of Practice and Procedure* to add sections addressing the duty of candor owned by persons who file complaints with the Commission seeking relief under section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337). The new sections set forth, in particular, the standard of conduct expected of complainants, the procedures for asserting and prosecuting allegations of wrongful conduct, and the sanctions which the Commission may impose upon those who are found to have violated the articulated standard.

Comments are requested on the proposed rules.

DATES: All comments must be received on or before December 22, 1988.

ADDRESSES: All comments concerning the proposed rules should be submitted to the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Comments should conform with Commission rule 201.8 (19 CFR 201.8).

FOR FURTHER INFORMATION CONTACT: Laurie B. Horvitz, Esq., 202-252-1107, or Tim Yaworski, Esq., 202-252-1906, Office of the General Counsel, U.S. International Trade Commission.

Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-252-1810.

SUPPLEMENTARY INFORMATION: Section 335 of the Tariff Act of 1930 (19 U.S.C. 1335) authorizes the Commission to adopt such reasonable procedures and rules and regulations as it deems necessary to carry out its functions and duties. Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), as amended by the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100-418, 102 Stat. 1107), expressly authorizes the Commission to impose by rule certain sanctions for abuse of process.

These proposed rules are being promulgated in accordance with the rulemaking provisions of section 553 of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), which entails the following steps: (1) Publication of a notice of proposed rulemaking; (2) solicitation of public comment on the proposed rules; (3) Commission review of such comments prior to developing final rules; and (4) publication of the final rules thirty (30) days prior to their effective date. *See* 5 U.S.C. 553.

The Commission has determined that the proposed rules do not constitute major rules for the purposes of Executive Order 12291, because they do not fall within the categories described in section (b) of the Executive Order.

Explanation of Proposed Rules

This rulemaking is prompted by allegations that certain complainants misrepresent or omit material facts in section 337 complaints. In response to these allegations, the Commission has determined that rules, developed after

the benefit of public comment, may be advisable to articulate the duty of candor owed by complainants to the Commission in the pre-institution phase of section 337 investigations.

The Standard of Conduct

The proposed rules set forth the standard of conduct expected of complainants prior to the institution of section 337 investigations. The standard applies to the conduct of complainants prior to institution because pre-institution representations of complainants are relief upon by the Commission when making institution decisions, there are costly and immediate consequences of institution, and complainants' pre-institution representations are made in the context of an essentially *ex parte* proceeding. As a result of the *ex parte* character of pre-institution proceedings and the limited time frame in which the Commission must make its institution decisions, there is often limited scrutiny of a complainant's submissions by the Commission and by persons with interests adverse to those of complainant. By contrast, submissions by all parties after institution are subjected to greater adversarial scrutiny and, as a result, the Commission often receives additional information which is helpful in evaluating and understanding the submissions of the parties.

The proposed duty of candor is violated when there is clear and convincing evidence of: (1) A failure to disclose material information, or a submission of false material information; and (2) an intent to mislead the Commission. Information is "material" when there is a substantial likelihood that a reasonable decisionmaker would have considered the nondisclosed or false information to be important in deciding whether to institute an investigation, not whether the information would have been dispositive. The "intent to mislead" element includes gross negligence. This standard is patterned after the standard of conduct articulated in 37 CFR 1.56 by the U.S. Patent and Trademark Office (PTO). Because practice before the Commission and the PTO differs in several respects, the Commission would not view PTO and court decisions interpreting the PTO standard as dispositive, or necessarily persuasive authority, in applying the Commission's standard of conduct.

Procedures for Alleging a Violation of the Standard of Conduct

If a section 337 investigation has been instituted by the Commission, the proposed rules provide that any party to the investigation may seek a duty of candor investigation. In addition, if the investigation is still pending before an ALJ, the ALJ may independently commence such an investigation. If the Commission has decided not to institute an investigation, the proposed respondents or the Commission's Office of Unfair Import Investigations (OUII) may seek commencement of a duty of candor investigation. In either event, the Commission may, at its own initiative, direct the Chief Administrative Law Judge to institute a duty of candor investigation.

Under the proposed rules, any duty of candor issue may be raised by motion to investigate during or after a section 337 investigation, provided that it is raised within 90 days after the Commission has issued a final determination on violation or within 90 days of any other final determination terminating the investigation. If no section 337 investigation has been instituted, any motion for investigation of duty of candor issues must be filed within 90 days after the Commission has voted not to institute a section 337 proceeding, provided that no motion to investigate will be entertained prior to the decision not to institute. These time limits are proposed in order to prevent a party from raising claims regarding the pre-institution conduct of a complainant many months or years after a case has terminated and thereby causing such allegations to be litigated on the basis of stale evidence, much of which may be based on the recollection of witnesses. The Commission expects that most facts relevant to a duty of candor issue will be discovered before or during the discovery phase of an investigation and, therefore, that the proposed time limits would not be excessively burdensome or unreasonable. However, the Commission recognizes that a rare case might arise where a complainant's wrongful conduct could not reasonably be discovered until after the prescribed period for raising duty of candor issues. In that event, a firm deadline for raising candor issues would benefit principally the wrongdoing complainant. Therefore, the proposed rules permit motions to investigate after the 90-day deadline if good cause is shown for the late submission. The moving party would be required to submit an affidavit stating that the motion is based on newly discovered evidence that could not have been discovered more expeditiously.

The proposed rules provide that each motion to investigate filed by a private party must be verified. This proposal is intended to discourage the filing of meritless motions. All motions should, at a minimum, be based on information and belief, must not be premised on mere speculation or conjecture, and must set forth the specific sanction sought by the movant. The articulation of a duty of candor is not intended to create merely another litigation tactic which private parties could utilize to harass and intimidate their adversaries or to retry issues of fact which already have been addressed by the ALJ in an initial determination on violation.

The proposed rules further provide that any motion to investigate must include allegations sufficient to warrant an investigation of the complainant's pre-institution conduct and must be specific. A failure to include specific and sufficient allegations in a motion to investigate could result in denial of the motion by an ALJ without the commencement of an investigation into the allegations.

If the motion to investigate is filed when a particular ALJ does not have jurisdiction over the investigation, the proposed rules provide that the motion be directed to the Chief Administrative Law Judge or such ALJ as he may designate. If a motion is filed while an ALJ has jurisdiction over an ongoing section 337 investigation, the motion would be filed with the ALJ. The ALJ presiding over the duty of candor motion would be authorized by the rules (1) to deny the motion if a *prima facie* case of conduct violating the commission's regulations on duty of candor is not alleged or a motion by a private party is not verified, (2) to consider the motion during the course of the ongoing investigation, if any, of complainant's allegations of a section 337 violation and issue a recommended determination (RD) reflecting his findings, or (3) at his discretion, to defer consideration of the duty of candor allegations until after he has issued an initial determination on violation or an initial determination otherwise terminating the investigation, provided that the ALJ would be required to issue an RD resolving all such allegations no later than 180 days after the motion to investigate is filed or an initial determination terminating the investigation is issued, whichever is later.

The proposed rules permit the ALJ to defer consideration of duty of candor issues because of the short statutory time limits that already restrict the amount of time within which ALJs must complete the evidentiary stage of section 337 investigations. To require an ALJ to consider and resolve all candor issues during the pendency of a section 337 hearing would, in many cases, be unduly burdensome and would hamper

the ALJ's ability to adequately address the violation issues. On the other hand, the Commission recognizes that certain duty of candor issues may be most efficiently addressed during the violation hearing and may be closely related to violation issues. The Commission therefore proposes that the ALJ be accorded discretion to decide when candor issues should be considered. However, recognizing that the Commission and the parties to an investigation have an interest in resolving duty of candor issues in a timely fashion, the Commission proposes a provision which would require ALJs to address such issues within 180 days after issuance of a determination which terminates an investigation, unless the motion to investigate candor issues is filed after such a determination is issued.

Findings of the Administrative Law Judge

Upon completion of any investigation of duty of candor issues, the proposed rules provide that the presiding ALJ is to issue an RD which includes specific findings of fact and a conclusion regarding whether there has been a violation of the duty of candor. If the ALJ finds that there has been a violation of the duty, he is to include in the RD a recommendation with respect to the appropriate sanctions, if any, for the violation. In addition, the proposed rules instruct the presiding ALJ to determine whether, if he has concluded that there has been *no violation* of the duty of candor, the motion to investigate the duty of candor issue was frivolous. The finding regarding frivolous motions is intended to discourage the filing of meritless motions for investigation of candor issues. If the ALJ finds that the motion to investigate the duty of candor issue was frivolous, he is also to recommend appropriate sanctions, if any, for the filing of a frivolous motion.

Sanctions for Violations of the Duty of Candor

The proposed rules list the sanctions available to the Commission when it finds that the duty of candor has been violated. The list of sanctions includes the following: (1) A private or public reprimand by the Commission; (2) temporary or permanent disqualification from practicing or appearing in any capacity before the Commission; (3) notification of appropriate professional associations and/or licensing authorities of the facts underlying the duty of candor investigation; (4) the award of costs and attorneys fees proximately caused by the misrepresentations or omissions which were the basis for the finding of a duty of candor violation; (5) referral to the U.S. Attorney for prosecution pursuant to 18 U.S.C. 1001; and (6) any combination of the listed sanctions. This list is included to provide parties with notice of the kinds of sanctions which could be imposed.

Sanctions for the Filing of Frivolous Motions to Investigate

The proposed rules also include a provision authorizing the award of sanctions when a private party has filed a frivolous motion to investigate allegations that a complainant has violated the duty of candor. These sanctions are set forth to discourage frivolous motions. Included in the list of sanctions is a private or public reprimand, disqualification from practicing or appearing in any capacity before the Commission, and notification of appropriate professional associations or licensing authorities of the facts underlying the duty of candor investigation. These sanctions would not be available against a Commission investigative attorney (IA) for several reasons. First, it is not expected that IAs will file frivolous motions because they lack the incentive to do so. The IAs represent the "public interest" and participate in proceedings in order to ensure that the record upon which the Commission bases its determination is as complete as possible. The legal positions of IAs are not dictated by private interests which are adverse to the interests of complainants and/or respondents. Therefore, frivolous motions to investigate by IAs are unlikely. Second, in the unlikely event that a frivolous motion were filed by an IA, the Commission believes that any sanction should be in the form of a personnel action and should be determined by the attorney's supervisors, not by an administrative law judge.

The proposed rule does not list the award of costs and attorneys fees as a sanction for frivolous motions because the Commission does not want to encourage parties to argue and litigate about the frivolity of motions to investigate simply because of the financial incentive of recovering fees. Instead, the proposed rule expressly includes sanctions which are intended to discourage frivolous claims without opening the floodgates to arguments about frivolous motions. Nonetheless, the Commission encourages comments on the advisability of including fees as a listed sanction for filing a frivolous motion to investigate.

List of Subjects in 19 CFR Part 210

Administrative practice and procedure, Business and industry, Candor, Customs duties and inspection, Imports, Investigations

For the reasons set forth in the preamble, the U.S. International Trade Commission proposes to amend 19 CFR Part 210 as follows:

PART 210—[AMENDED]

1. The authority citation for Part 210 continues to read as follows:

Authority: 19 U.S.C. 1333, 1335, 1337.

2. Subpart H, consisting of §§ 210.80 through 210.85, is added to read as follows:

Subpart H—Complainants' Pre-Institution Duty of Candor

Sec.

Subpart H—Complainants' Pre-Institution Duty of Candor

§ 210.80 Purpose and applicability of subpart.

This subpart defines the duty of candor owed by complainants in section 337 investigations during the pre-institution phase of such investigations. The articulation by rule of such a duty is intended to clarify that complainants cannot misrepresent and/or omit material facts in pre-institution submissions to the Commission and that the Commission will sanction such conduct if it violates the articulated duty.

§ 210.81 Standard of conduct.

(a) *The duty of candor is owed by the following:* (1) The complainant and all individuals who verify the complaint;

(2) Counsel for the complainant who prepares and prosecutes the complaint prior to the institution of a section 337 investigation; and

(3) All other individuals who are substantially involved in the preparation and prosecution of the complaint prior to institution.

(b) *Standard of Conduct.* (1) Such persons shall not, with an intent to mislead the Commission, fail to disclose material information to the Commission during the pre-institution phase of section 337 investigations or submit false material information during that phase of an investigation. Information is "material" when there is a substantial likelihood that a reasonable

decisionmaker would have considered the nondisclosed or false information to be important in deciding whether to institute an investigation. The "intent to mislead" element includes gross negligence.

(2) Violation of this duty shall be established with clear and convincing evidence.

§ 210.82 Procedures for alleging a violation of standard of conduct.

(a) *Parties who may request an investigation of complainant's candor.* (1) If a section 337 investigation has been instituted by the Commission, any party to the investigation may seek a duty of candor investigation. In addition, if the investigation is still pending before an administrative law judge, the administrative law judge may independently commense such an investigation.

(2) If the Commission has decided not to institute a section 337 investigation, the proposed respondents or the Office of Unfair Import Investigations may seek commencement of a duty of candor investigation.

(3) In either event, the Commission may, at its own initiative, direct the Chief Administrative Law Judge to institute a duty of candor investigation.

(b) *Timing of motions to commence an investigation.* (1) If a section 337 investigation has been instituted by the Commission, a duty of candor issue may be raised by motion to investigate during or after the section 337 investigation, provided that the motion must be filed on or before the ninetieth (90th) day after the Commission has issued a final determination on violation or on or before the ninetieth (90th) day after any other final determination termining the investigation.

(2) If no investigation has been instituted, any motion for investigation must be filed on or before the ninetieth (90th) day after the Commission has voted not to institute the investigation.

(3) Notwithstanding paragraphs (b)(1) and (2) of this section a motion to investigate a duty of candor issue may be filed after the ninety (90)-day deadlines set forth therein if the motion is accompanied by an affidavit stating that the motion is based upon newly discovered evidence and that the evidence could not have been discovered earlier. Specific facts in support of these statements must be alleged.

(c) *Requirements for motions to investigate.* (1) Each motion by a private party to investigate must be made under oath by the moving party or his duly authorized officer, attorney, or agent, with the name, address, and phone number of the party and any such officer, attorney, or agent.

(2) Each motion must be based on personal knowledge or on information and belief, must include specific allegations sufficient to warrant an investigation of the complainant's pre-institution conduct and submissions, and must set forth the specific sanction requested by the movant.

(d) *Filing of the motion and the timing of Commission consideration.* (1) All such motions, whether brought at any time during an investigation, after the conclusion of an investigation, or after the Commission has decided not to institute an investigation, shall be addressed to and ruled upon by the presiding administrative law judge, or if the investigation is not before a presiding administrative law judge, by the Chief Administrative Law Judge or such administrative law judge as he may designate.

(2) Upon receipt of such a motion, the administrative law judge may deny the motion if it fails to satisfy the requirements of § 210.82(c), consider the motion during the course of the investigation, if any, of complainant's allegations of a section 337 violation and issue a recommended determination regarding the duty of candor issues, or at his discretion, defer consideration of the duty of candor allegations until after he has issued an initial determination on violation or an initial determination otherwise terminating the section 337 investigation, provided that the administrative law judge shall issue a recommended determination resolving all duty of candor allegations no later than one hundred and eighty (180) days after the motion to investigate was filed or the administrative law judge issued a determination terminating the investigation, whichever is later.

§ 210.83 Findings of the administrative law judge

(a) Upon completion of any investigation of duty of candor issue, the administrative law judge is to issue a recommended determination which includes specific findings of fact and an ultimate conclusion regarding whether there has been a violation of the duty of candor owed to the Commission. If the administarative law judge finds that there has been a violation of the duty, he is to include in the recommended determination a recommendation with respect to the appropirate sanctions, if any, for the violation and, if appropriate, any specific findings of fact regarding the sanctions issue.

(b) If he has concluded that there has been no violation of the duty of candor, the administrative law judge's recommended determination is to include a conclusion regarding whether or not the motion to investigate the duty of candor issue was frivolous and specific findings of fact relating to that conclusion. If the administrative law judge finds that the motion to investigate the duty of candor issue was frivolous, he is also to recommend appropriate sanctions, if any, for the filing of the frivolous motion.

§ 210.84 Sanctions for violations of the duty of candor.

The following sanctions may be imposed by the Commission in the event that it determines that the duty of candor, as defined in section 210.81, has been violated:

(a) A private or public reprimand by the Commission;

(b) Temporary or permanent disqualification from practicing or appearing in any capacity before the Commission;

(c) Notification of appropriate professional associations and/or licensing authorities of the facts underlying the duty of candor investigation;

(d) The award of costs and attorneys fees proximately caused by misrepresentations or omissions which resulted in the finding of a duty of candor violation;

(e) Referral to the U.S. Attorney for prosection pursuant to 18 U.S.C. 1001; and

(f) Any combination of the sanctions listed above.

§ 210.85 Sanctions for the filing of frivolous motions to investigate.

The following sanctions are available to the Commission when a private party has filed a frivolous motion to investigate allegations that a complainant has violated the duty of candor;

(a) A private or public reprimand by the Commission;

(b) Temporary or permanent disqualification from practicing or appearing in any capacity before the Commission;

(c) Notification of appropriate professional associations and/or licensing authorities of the facts underlying the duty of candor investigation; and

(d) Any combination of the sanctions listed above.

By order of the Commission.

Kenneth R. Mason,

Secretary.

Issued: October 31, 1988.

[FR Doc. 88-25559 Filed 11-4-88; 8:45 am]

BILLING CODE 7020-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 182 and 184

[Docket No. 85N-0548]

Proposed Affirmation of GRAS Status of High Fructose Corn Syrup

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that high fructose corn syrup is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated on the basis of the agency's evaluation of six industry petitioners and of the agency's comprehensive safety review of corn sugar, corn syrup, invert sugar, and sucrose. Published elsewhere in this issue of the **Federal Register** is a final rule affirming the GRAS status of corn sugar, corn syrup, invert sugar, and sucrose.

DATE: Written comments by January 6, 1989.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 230857.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Listing of High Fructose Corn Syrup as GRAS in Part 182

In the **Federal Register** of February 8, 1983 (48 FR 5716, FDA published a regulation in 21 CFR Part 182 that listed high fructose corn syrup as GRAS for use in food. FDA published this regulation in response to six industry petitions that requested GRAS status for certain insoluble glucose isomerase enzyme preparations used to make high fructose corn syrup and for the manufactured product itself.

The basis for listing high fructose corn syrup in Part 182 was that (1) this substance is made with enzyme preparations that the agency had affirmed as GRAS, and (2) the saccharide composition (glucose to fructose ratio) of high fructose corn syrup is approximately the same as that of honey, invert sugar, and the disaccharide sucrose. In addition, the minor components (primarily higher saccharides of glucose) of high fructose corn syrup are also found at similar levels in corn syrup and corn sugar which are already on the GRAS list. Therefore, FDA concluded that high fructose corn syrup is as safe for use in food as sucrose, corn sugar, corn syrup, and invert sugar. However,, because the agency had not made a decision on whether it would affirm the latter ingredients as GRAS, it could not make this decision for high fructose corn syrup at that time.

The agency stated that when it completed its comprehensive safety review of corn sugar (dextrose), corn syrup, invert sugar, and sucrose, it would determine whether the data on these substances provided an adequate basis to affirm the GRAS status of high fructose corn syrup.

B. Identity of High Fructose Corn Syrup

Paragraph (a) of 21 CFR 182.1866 describes high fructose corn syrup as "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 syrup hydrolystate by partial enzymatic conversion of glucose (dextrose) to fructose using an insoluble glucose isomerase enzyme preparation described in § 184.1374 of this chapter."

The proposed regulation applies only to the high fructose corn syrup that meets the description as specified in 21 CFR 182.1866(a). The agency is aware that there are other products on the market that are also called "high fructose corn syrup" but that have fructose contents of greater than 43 percent (dry weight). These products generally contain either 55 percent fructose (HFCS-55) or 90 percent fructose (HFCS-90) on a dry weight basis. FDA is not proposing to affirm these products as GRAS because, as discussed later in this document, their manufacture involves the use of processing materials that are not used in making the 43 percent fructose product, and the agency does not have adequate information on these materials to assess the safety of their residual levels in these products.

C. Definitions

To clarily its discussion of the proposed GRAS affirmation of high fructose corn syrup, the agency is defining and explaining important terms used in this document.

The term "sugar" is used to refer to any of the mono- and disaccharides glucose, fructose, sucrose, and maltose, which are found in sucrose, corn sugar, corn syrup, invert sugar, and high fructose corn syrup. The term "sugar" has traditionally been used by consumers and by the agency (see 21 CFR 145.3(f), 146.3(f), and 170.3(n)(41)) as a synonym for the sweetener sucrose. In this document, however the sweetener sucrose is identified as "sucrose." The agency will use the term "sugars" to describe mixtures of mono- and disaccharides and collectively all forms of sugar present in a food.

FDA will use the term "sweetener" to refer to any one or more of the carbohydrate food ingredients sucrose, corn sugar, corn syrup and solids, invert sugar, high fructose corn syrup, honey, and other edible syrups. The term "sweetener", as used in this document, is not intended to include any other nutritive or nonnutritive sweeteners that are added to food.

High fructose corn syrup, as described earlier, is composed primarily of approximately equimolar amounts of the monosaccharides glucose and fructose with some higher molecular weight saccharides. Sucrose is the disaccharide of glucose and fructose. Invert sugar is composed of glucose, fructose, and sucrose. Corn sugar, commonly referred to as dextrose, is crystalline α-D-glucose. Corn syrup contains glucose and maltose (a disaccharide of glucose), as well as higher molecular weight saccharides. These five ingredients may also contain water and residues from the carbohydrate source material and from processing.

II. The Safety Review of High Fructose Corn Syrup

A. Sources of Information for the Safety Evaluation of High Fructose Corn Syrup

In evaluating the safety of high fructose corn syrup as a GRAS ingredient, the agency used the following sources of information:

1. GRAS Affirmation Petitions on High Fructose Corn Syrup (4G0042, 6G0060, 7G0080, 7G0084, 7G0086, and 1G0271)

These petitions describe high fructose corn syrup as 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. The petitions stated that high fructose corn syrup is made by the action of a glucose isomerase enzyme preparation on high dextrose equivalent corn syrup.

Each of the five petitions requested GRAS affirmation for a specific glucose isomerase preparation derived from one of five microbial species. The identity of the enzyme preparation was based on the identity of the microbial source and the identity of the materials used to produce and immobilize the enzyme preparation.

The petitions provided precise taxonomic classification of each microbial source. The petitions contained information that described the method and materials used to produce and to immobilize the enzyme-containing cellular materials.

The petitions contained general manufacturing information for high fructose corn syrup that provides a basis upon which to determine the residual levels of enzyme preparation that would occur in high fructose corn syrup. This information demonstrated that, under the current methods, only very small amount of enzyme preparation would enter the product. The enzyme preparation is extensively washed to remove processing materials before it is used. In addition, only relatively small amounts of the washed enzyme preparation are used to catalyze the conversion of large quantities of glucose syrup.

The petitions also contained published data on the microbial sources of the enzyme preparation as well as unpublished animal feeding studies that established safe levels of the enzyme preparation in the product. A more detailed discussion of the identity of high fructose corn syrup, of its method of manufacture, and of the rationale for the agency's safety determination for the enzyme preparations used in the manufacture of high fructose corn syrup is found in the final rule published in the **Federal Register** of February 8, 1983 (48 FR 5716).

2. The Select Committee Report: "Evaluation of the Health Aspects of Corn Sugar (Dextrose), Corn Syrup, and Invert Sugar as Food Ingredients" (SCOGS–50) (Ref. 1)

This report is relevant to the safety of high fructose corn syrup because any adverse health effects associated with the consumption of corn sugar, corn syrup, and invert sugar are likely also to be associated with high fructose corn syrup. High fructose corn syrup, corn sugar, and corn syrup all contain glucose, maltose, and higher saccharides, as well as residues from the processing aids and from the corn used to manufacture these sweeteners. Both high fructose corn syrup and invert sugar contain glucose and fructose. Therefore, any adverse health effect of consumption of corn sugar, corn syrup, or invert sugar may also occur from consumption of high fructose corn syrup.

The report of the Select Committee also contains a limited opinion and conclusion regarding the safety of high fructose corn syrup. The report states that the consumption of dextrose and corn syrup has increased markedly in recent years and a major part of the increase resulted from the introduction of high fructose corn syrup. The Select Committee cited predictions that high fructose corn syrup would replace 30 percent of the applications for sucrose and invert sugar. In the opinion of the Select Committee there is no evidence such replacement would have an adverse effect on public health. A more detailed description of the findings and the conclusions of the Select Committee on the safety of corn sugar, corn syrup, and invert sugar was published in the agency's proposal to affirm the GRAS status of these food ingredients (47 FR 53917; November 30, 1982).

3. The Select Committee Report: "Evaluation of the Health Aspects of Sucrose as a Food Ingredient" (SCOGS–69) (Ref. 2)

Sucrose is a disaccharide that is hydrolyzed in the intestine and is absorbed as its component monosaccharides, glucose and fructose. High fructose corn syrup also is essentially a mixture of glucose and fructose in approximately equal proportions. Because of the similarity in sugars composition between these two sweeteners at the time of absorption, any reported adverse health effects of sucrose consumption are likely to occur also from consumption of high fructose corn syrup. Thus, the Select Committee's report on sucrose is relevant to the safety evaluation of high fructose corn syrup. A description of the findings and the conclusions of the Select Committee on the safety of sucrose was published in the agency's proposal to affirm the GRAS status of sucrose as a food ingredient (47 FR 53923; November 30, 1982).

4. The Task Force Report: "Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners" (Ref. 3)

In November 1983, the agency established the Sugars Task Force composed of scientists from FDA's Center for Food Safety and Applied Nutrition to update the Select Committee's safety reviews of corn sugar, corn syrup, and invert sugar and of sucrose.

In its safety evaluations of these substances, the Select Committee found: (1) That the safety of a specific sweetener can be assessed only as part of a safety assessment of total sweetner consumption (see the Select Committee's conclusions for sucrose and for corn sugar, corn syrup, and invert sugar); and (2) that the safety of an individual sweetener is contingent upon the safety of the "simple sugars" that it contains (see especially the Select Committee's conclusion for corn sugar, corn syrup, and invert sugar). Based on these findings, the agency charged the Task Force to conduct a single safety review of all sweeteners.

The Task Force review focused on the sugars contained in the sweeteners rather than on the sweeteners themselves. It used the conclusions it reached on the safety of the sugars to assess the safety of the sweeteners that contain these sugars.

The Task Force has completed its safety review. FDA has placed a copy of the Task Force's report on file in the Dockets Management Branch (address above) in Docket No. 76N–0141. This report contains safety data on fructose, glucose, maltose, and sucrose that are relevant to a safety assessment of high fructose corn syrup. It also contains an assessment of various sugars intakes and sweetener availability and thereby provides a basis for estimating current consumption of high fructose corn syrup.

A more complete description of the Task Force's safety review and of the conclusions of the Task Force regarding the safety of the dietary sugars (glucose, fructose, sucrose, and maltose) is provided elsewhere in this issue of the **Federal Register** in the final rule that affirms the GRAS status of corn sugar, corn syrup, invert sugar, and sucrose.

B. Findings of the Safety Review for High Fructose Corn Syrup

1. Consumption of High Fructose Corn Syrup

The Task Force, in its report, estimated that in 1984 the average daily intake of sugars from high fructose corn syrup was 19 grams per person per day, and that for the 90th percentile consumers of total sugars, it was 43 grams per person per day (Ref. 3). Because the sugars in high fructose corn syrup (glucose, fructose, and maltose) represent approximately 98 percent of its dry weight, the agency concludes that these values represent appropriate estimates of the average daily intakes of high fructose corn syrup itself on a dry weight basis.

In its report, the Task Force estimated intakes of the sugars glucose, fructose, sucrose, and maltose by combining food consumption data from the U.S. Department of Agriculture (USDA) Nationwide Food Consumption Survey of 1977–1978 with sugars composition data (Ref. 3). For details of how the Task

Force made its estimate see the final rule, Ref. 2.

It should be noted that the consumer exposure data relating to high fructose corn syrup consumption presented in the Task Force report included current use of HFCS–55. The exposure data, however, did not include HFCS–90 because this product is not currently used in a significant amount, and data required to make intake estimates of this product are not available (Ref. 3).

The Task Force also assessed trends in sweetener availability based on USDA disappearance data. Disappearance data for sweeteners represent estimates of domestic shipments (deliveries) of sweeteners by refiners and importers to primary buyers, such as food industries, trades, wholesalers, and retailers (Ref. 3). The data thus represent approximate estimates of the total amount (dry weight) of sweeteners available for consumptoin by the U.S. population and not the amount of sweeteners actually consumed.

The Task Force's assessment of USDA disappearance data for total sweeteners showed that, since 1970, availability of total sweeteners has been reasonably constant (Ref. 3). The same data show, however, that during this period, there was a significant change in types of sweeteners used. High fructose corn syrup usage increased rapidly, accompanied by a complete decrease in sucrose usage. These data also show that high fructose corn syrup usage has now plateaued, and no further increase is expected in the near future (Ref. 3). Based on this projection, the agency anticipates little future change in exposure to high fructose corn syrup.

2. Safety of High Fructose Corn Syrup

In its reports evaluating the safety of sucrose and the safety of corn sugar, corn syrup, and invert sugar, the Select Committee concluded (Refs. 1 and 2) that sucrose, glucose, and fructose (and therefore corn sugar, corn syrup, high fructose corn syrup, and invert sugar) are cariogenic. However, other than the contribution of dental caries, the Select Committee found no evidence that sucrose, corn sugar, corn syrup, and invert sugar are a hazard to the public when they are used in the manner practiced and at the levels used at the time of the reports. The Select Committee noted, however, that it could not determine whether an increase in total sweetener consumption (the total of sucrose, corn syrup, and invert sugar) would constitute a dietary hazard.

In its report on corn syrup, corn syrup, and invert sugar, the Select Committee also expressed the opinion that (Ref. 1):

> High fructose corn syrups are predicted to increase in production and to replace sucrose and invert sugar in up to 30 percent of their applications by 1980–85, based largely on relative costs. There is no evidence that such replacement, *per se*, would have an adverse effect on public health.

This opinion is based on the assumption that high fructose corn syrups will be formulated in the present manner, i.e., approximately equimolar mixture of glucose and fructose. It does not extend to the use of fructose syrups or other types of high fructose corn syrups that are predominantly fructose, because these syrups may have health effects that differ substantially from the types manufactured currently.

In its report evaluating the safety of sugars (glucose, fructose, sucrose, and maltose), the Task Force concluded that (Ref. 3):

(1) Evidence exists that sugars, as they are consumed in the American diet, contribute to the development of dental caries.

(2) Other than the contribution to dental caries, there is no conclusive evidence in the available information on sugars that demonstrates a hazard to the general public when sugars are consumed at the levels that are now currnet and in the manner now practiced.

The agency evaluated the safety issues related to sweetener consumption raised in the Select Committee's reports on sucrose and on corn sugar, corn syrup, and invert sugar and in the Task Force report. In particular, it considered the issue of the association between consumption of these sweeteners (or sugars) and the incidence of dental caries.

The agency recognized that the Task Force's conclusions regarding dental caries reinforce the Select Committee's conclusions and establish more definitely the association between sugars consumption and dental caries incidence. Yet, the agency decided to affirm the GRAS status of the use of sucrose, corn sugar, corn syrup, and invert sugar, despite their contribution to dental caries formation. The agency concluded that while the Task Force's findings on dental caries supported the Select Committee's findings, the Task Force's findings did not show that the association between sugars consumption and dental caries had become a more significant health problem than it had been in 1976. The Task Force report showed that total exposure to sweeteners had not changed since the Select Committee's report. Moreover, it showed that caries incidence in the United States had declined in the past decade. The data reviewed in the Task Force report suggest that further developments in caries prevention should facilitate this decline in the future.

For these reasons, the agency has concluded that the Task Force's review did not provide any basis for modifying the 1982 proposed GRAS affirmation of corn sugar, corn syrup, invert sugar, and sucrose.

3. Effects of Increased Consumption of Fructose

The major change in sugars consumption that has occurred as a result of the introduction of high fructose corn syrup containing approximately equimolar amounts of glucose and fructose is the increased consumption of glucose and fructose as monosaccharides as opposed to their consumption as the disaccharide sucrose.

The agency has no significant safety concern about the increase in glucose consumption and would be concerned only if this increase was so great as to cause a nutritional imbalance. Glucose is a normal body nutrient and is the main source of energy for living organisms, including humans. Glucose in a polymeric form (starch) is a normal macronutrient in the human diet.

Fructose, however, does not occupy a similar place in the human diet and metabolism. Before the introduction of high fructose corn syrup, the major sources of added dietary fructose were sucrose and honey. Thus, the major question that must be answered in a safety evaluation of high fructose corn syrup is the effect of consumption of high fructose corn syrup on total fructose consumption.

The Task Force considered current levels of fructose intake, the trend in high fructose corn syrup intake, and the health problems that are associated with the current and the anticipated levels of fructose intake.

As part of its safety assessment of fructose, the Task Force estimated the level of consumption of this sugar in 1984 (Ref. 3). It found that the average daily intake of added fructose was 10 grams per day, and that the 90th percentile average daily intake of added fructose was 23 grams per day. The Task Force in its safety evaluation of fructose found that these intake levels are safe (except for contributing to dental caries) based on safety data reviewed for its report (Ref. 3).

The Task Force assessed the changes in availability of fructose added to food. Based on the evaluation of USDA disappearance data, the Task Force found that the availability of high fructose corn syrup increased since

1970. This increase in the high fructose corn syrup usage has resulted in an increase in the availability of fructose added to the food supply. However, the true increase in fructose availability is smaller than that which appears from the increase in the high fructose corn syrup usage because two thirds of the high fructose usage replaced the sucrose usage in soft drinks, and most of the sucrose in soft drinks exists as glucose and fructose (invert sugar), not as sucrose. Thus, part of the increase in fructose availability acutally replaced the fructose that was already existing in the food supply (Ref. 3). Further, the increase in the high fructose corn syrup usage has been accompanied by a comparable decline in the availability of sucrose. Because sucrose splits into glucose and fructose before absorption for use by the body, the total body load of fructose has not changed much due to use of high fructose corn syrup as currently practiced.

C. Conclusions on the GRAS Status of High Fructose Corn Syrup

Based on the findings of the safety reviews of both the Select Committee and the Task Force, the agency finds that evidence exists that high fructose corn syrup, as it is consumed in the average American diet, contributes to the formation of dental caries.

The agency also finds that there is no convincing evidence in the available information on high fructose corn syrup that demonstrates a hazard to the public, other than dental caries, when high fructose corn syrup is consumed at the levels that are now current and in the manner now practiced.

This conclusion is based on the following:

(1) Data in the Task Force report that show that use of high fructose corn syrup has not resulted in an increase in the consumption of total sugars in the United States as a result of the substitution of high fructose corn syrup for other sweeteners, primarily sucrose.

(2) The safety of the monosaccharides (i.e., glucose and fructose) in high fructose corn syrup (containing equimolar amounts of glucose and fructose) is comparable to the safety of sugars in invert sugar. It is also related to the safety of sucrose. Consumption of all three sweeteners results in the absorption and metabolism of glucose and fructose in an approximately equimolar ratio. Thus, consumption of high fructose corn syrup (containing equimolar amounts of glucose and fructose) is not expected to alter the identity, level, or ratio of monosaccharides that are available for absorption and metabolism from the food supply.

(3) Insoluable glucose isomerase enzyme preparations used in the manufacture of high fructose corn syrup arre GRAS (§ 184.1372) (48 FR 5716; February 8, 1983).

(4) The safety of the minor components (e.g., the higher saccharides and other residues from corn and corn processing) of high fractose corn syrup is comparable to the safety of these components in corn sugar and corn syrup (which have been affirmed as GRAS for use in food). These marterials are present in the original corn syrup used to make high fructose corn syrup and their presence and concentration (gram per gram dry weight) are not altered by the high fructose corn syrup manufacturing process.

Based on these findings, the agency tentatively concludes that it can affirm that the high fructose corn syrup described in 21 CFR 182.1866 is generally recognized as safe as a direct human food ingredient.

In reaching this tentative conclusion, the agency notes that its proposed GRAS affirmation of high fructose corn syrup does not cover a major commerical product that is 55 percent (dry weight) fructose, HFCS–55. The petitions on which the GRAS affirmation of high fructose corn syrup is based did not include HFCS–55. However, the agency is aware of the product, and that the manufacture of HFCS–55 includes processing procedures and materials that are not used to prepare the 43 percent fructose HFCS (HFCS–43) that is the subject of this action. The agency has no information on which to assess the identity and possible residue levels of these processing materials in the HFCS–55 final product. Therefore, the agency cannot adequately assess the safety of that product.

The agency's exposure estimate for high fructose corn syrup did, however, include exposure to HFCS–55. Furthermore, the agency concedes that most of the components found in HFCS–43 (approximately equimolar mixtures of glucose and fructose, residues from corn syrup, and residues from the enzyme preparations used to make high fructose corn syrup) are also found in HFCS–55. Therefore, the safety evaluation of the major components in HFCS–43 is also applicable to HFCS–55. Accordingly, the agency would consider including HFCS–55 in its final rule affirming the GRAS status of high fructose corn syrup if it receives, as comments on this proposal, adequate information on how HFCS–55 is manufactured to allow the agency to identify possible residues from processing materials and thereby to ensure that the levels of those residues in the final product are safe.

The proposed GRAS affirmation of high fructose corn syrup also does not include the 90 percent fructose HFCS (HFCS–90), which is also a commercially available product. This product contains a substantially different ratio of glucose to fructose than either HFCS–43 or HFCS–55. HFCS–90 is not included in this rulemaking because the agency does not have adequate information on the processing materials used to make this ingredient to assess the safety of residual levels of the processing materials in the final product. Furthermore, FDA did not inlcude HFCS–90 in the agency's exposure estimate for high fructose corn syrup. The agency is aware of only minor uses of HFCS–90 as an ingredient in low calorie foods. Finally, the agency's safety review of the sugars components of high fructose corn syrup does not cover this product because HFCS–90 does not contain approximately equimolar amounts of glucose and fructose. Thus, additional data on the effects of fructose consumption that is not balanced with glucose consumption would be needed to assure the safety of this product. The agency concludes that appropriate consideration of GRAS status of this product would be through the petition process (21 CFR 170.35).

D. Conditions of GRAS Affirmation

The agency is proposing to affirm the GRAS status of high fructose corn syrup in accordance with 21 CFR 184.1(b)(1). The proposed GRAS affirmation regulation is based on the conclusions of the Select Committee's report and Task Force report on sweeteners.

The agency's conclusion on the use of high fructose corn syrup is based, in large part, on the agency's conclusions on the safety of total sweetener consumption. The agency's conclusion that such consumption is GRAS is predicated on the assumption that the consumption and availability of total sugars will remain at current levels.

Usually when the safety of possible expanded consumption of a substance cannot be ascertained, FDA proposes to establish specific limitations on use of the substance. For corn sugar, corn syrup, invert sugar, and sucrose, however, the agency concluded that limitation on their use would not effectively prevent an increase in total dietary sugars consumption for the following reasons:

(1) The concern of the Select Committee (and of the Task Force) relative to sweetener consumption and

adverse affects was for total sweetener consumption.

(2) The use of these sweeteners is extremely variable within each of the 43 food categories listed in § 170.3(n). Thus, even if the agency were to adopt maximum use levels, it would not prevent manufacturers from increasing the amount of these sweeteners in a particular product in a food category to the level established by the limitation.

(3) Establishment of specific limitations for these sweeteners would not prevent the excessive consumption of these ingredients or other dietary sugars that results from voluntary selection of those foods that have a high sugars content.

For these reasons, the proposed regulations on sucrose, corn sugar, corn syrup, and invert sugar specify that the ingredients are used in food with no limitation other than current good manufacturing practice in accordance with § 184.1(b)(1) (see 47 FR 53917 and 53923; November 30, 1982).

For similar reasons, FDA is proposing to not establish limitations on the use of high fructose corn syrup in food. Given the safety conclusions of both the Select Committee and the Task Force regarding total sweetener consumption, the finding of the Task Force that the level of total sweetener consumption has not changed, and the interchangeability of sweetener use, the agency tentatively concludes that there is no basis for establishing conditions of use for high fructose corn syrup that are different from those established for the other sweeteners. Therefore, the agency is proposing to affirm the GRAS status for the use of high fructose corn syrup in food with no limitation other than current good manufacturing practice. The agency also proposes to amend 21 CFR 184.1372 *Insoluable glucose isomerase enzyme preparations* by removing the Part 182 citation for high fructose corn syrup (21 CFR 182.1866) and replacing this citation with the new Part 184 citation (21 CFR 184.1866).

Food-grade specifications do not exist for high fructose corn syrup at the present time. The agency will work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for this ingredient. When acceptable specifications are developed, the agency will incorporate them into this regulation. Until specifications are developed, FDA has determined that the public health will be adequately protected if commercial high fructose corn syrup complies with the description in the proposed regulation and is of food-grade purity in accordance with 21 CFR 170.30(h)(1) and 182.1(b)(3).

III. Impact Analysis

The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to maintain current known uses of the substance covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal and has determined that the final rule, if promulgated, will not be a major rule as defined by the Order.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch.

IV. Comments

Interested persons may, on or before January 6, 1989, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch, 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), Cron 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., Irausquin, H. and Park, Y. K. "Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners," Report of Sugars Task Force, 1986, *Journal of Nutrition*, 116 (115):51–5216, 1986.

4. Kirk-Othmer Encyclopedia of Chemical Technology, 3d Ed., Vol. 22, p. 510.

List of Subjects

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Parts 182 and 184 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 182 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

§ 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(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

4. Section 184.1372 is amended by revising the first sentence in paragraph (a) to read as follows:

§ 184.1372 Insoluable glucose isomerase enzyme preparations.

(a) Insoluable glucose isomerase enzyme preparations are used in the production of high fructose corn syrup as described in § 184.1866 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 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.

(b) FDA is developing food-grade specifications for high fructose corn syrup in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of purity suitable for its intended use.

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

Dated: October 31, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-25584 Filed 11-4-88; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8-R

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Application of the Medicare Economic Index

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule will amend Part 199 of Title 32, the regulation which governs CHAMPUS, by implementing Section 8019 of the Department of Defense Appropriation Act for 1989, Pub. L. 100-463. This section limits increases in the CHAMPUS prevailing charges for physician and other authorized individual providers of medical care to the extent justified by economic changes as reflected in appropriate economic index data similar to that used under Medicare. The amended 32 CFR Part 199 would employ the Medicare Economic Index to limit the increases in prevailing charges.

DATE: Written public comments must be received on or before December 7, 1988.

ADDRESS: Send comments to the Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Office of Program Development, Aurora, CO 80045-6900.

For copies of the **Federal Register** containing this notice, contact the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783-3238.

The charge for the **Federal Register** is $1.50 for each issue payable by check or money order to the Superintendent of Documents.

FOR FURTHER INFORMATION CONTACT: Tariq S. Shahid, Office of Program Development, OCHAMPUS, telephone (303) 361-3587.

To obtain copies of this document, see the *"ADDRESS"* section above.

SUPPLEMENTARY INFORMATION: In FR Doc. 77-7834, appearing in the **Federal Register** on April 4, 1977 (42 FR 17972), the Office of the Secretary of Defense published its regulation, DoD 6010.8-R, "Implementation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)," as Part 199 of this title. The 32 CFR Part 199 (DoD 6010.8-R) was reissued in the **Federal Register** on July 1, 1986 (51 FR 24008).

I. Background

Currently, for the services of physicians and other authorized individual professional providers, the regulation provides that the allowable charge for covered care shall be the lower of: (1) The billed charge for the service; or (2) the prevailing charge level that does not exceed the amount equivalent to the 60th percentile of billed charges made for similar services in the same locality during the base period. Section 8019 of the Department of Defense Appropriation Act for Fiscal Year 1989, Pub. L. 100-463, requires that

> None of the funds contained in this Act available for the Civilian Health and Medical Program of the Uniformed Services under the provisions for section 1079(a) of title 10, United States Code, shall be available for reimbursement of any physician or other authorized individual provider of medical care in excess of the lower of: (a) the eightieth percentile of the customary charges made for similar services in the same locality where the medical care was furnished, as determined for physicians in accordance with section 1079(h) of title 10, United States Code; or (b) the allowable amounts in effect during fiscal year 1988 increased to the extent justified by economic changes as reflected in appropriate economic index data similar to that used pursuant to title XVIII of the Social Security Act.

Accordingly, beginning approximately January 1, 1989, increases in the CHAMPUS prevailing charges in effect during fiscal year 1988 for physicians and other authorized individual providers will be limited based on application of the Medicare Economic Index (MEI).

On September 29, 1988, we published in the **Federal Register** (53 FR 38050) a notice to defer update of CHAMPUS prevailing charge levels for professional services originally to be effective October 1, 1988. This notice specified that the deferral of the update will last for 12 months unless CHAMPUS implements the MEI method to limit growth in prevailing charges.

Effective approximately January 1, 1989, this proposed rule will implement the provisions of Pub. L. 100-463, adopting the MEI under CHAMPUS and lifting the freeze on prevailing charge levels. With the adoption of the MEI, the CHAMPUS fee screen year (the 12 month period beginning on the date the profiles are updated) will also be changed from a fiscal year to a calendar year.

II. Medicare Economic Index (MEI)

In 1972, in response to concerns about rising physician fees reimbursed under Part B of the Medicare program, Congress mandated that an additional fee limit be included in the calculation of "reasonable" charges. Under Section 224 of the Social Security Act Amendments of 1972 (Pub. L. 92-603), the prevailing charge—an amount equal to the maximum reasonable charge allowed physicians for a specific procedure in a specific locality—could exceed the July 1972-June 1973 prevailing charge only by an amount reflected by an index of changes in physicians' operating expenses and earnings levels. This index is known as the Medicare Economic Index (MEI). Under Medicare, in the case of physicians' services only, annual increases in prevailing charges are provided to account for inflation, but only to the extent that there are updates in the MEI. The MEI updates have progressively increased the initial prevailing charge level that was established for the (then) fiscal year ending June 30, 1973.

The Omnibus Budget Reconciliation Act of 1987 established the MEI for 1989 at 3.0 percent for primary care services and 1.0 percent for other services. Primary care services were defined in the accompanying Conference Report to be office medical visits, home medical visits, emergency department services, and skilled nursing, intermediate care, long-term care facility, nursing home, boarding home, domiciliary or custodial care visits.

CHAMPUS will be following the Medicare procedure in this regard, subject to changes based on differences in the CHAMPUS and Medicare programs. Under CHAMPUS, we