Auburn Way South to its intersection with State Highway 18, thence westerly along Highway 18 to its intersection with A Street S.E., then southerly along A Street S.E. to its intersection with the King County Line, then westerly along the King County Line to its intersection with the waters of Puget Sound and then northerly along the shores of Puget Sound to its intersection with N.W. 205th Street, the point of beginning, all within the County of King, State of Washington), Anacortes, Bellingham, Everett, Friday Harbor, Neah Bay, Olympia, Port Angeles, Port Townsend, and the territory in Tacoma beginning at the intersection of the westernmost city limits of Tacoma and The Narrows and proceeding in an easterly, then southerly, then easterly direction along the city limits of Tacoma to its intersection with Pacific Highway (U.S. Route 99), then proceeding in a southerly direction along Pacific Highway to its intersection with Union Avenue Extended and continuing in a southerly direction along Union Avenue Extended to its intersection with the northwest corner of McChord Air Force Base, then proceeding along the northern, then western, then southern boundary of McChord Air Force Base to its intersection, just west of Lake Mondress, with the northern boundary of the Fort Lewis Military Reservation, then proceeding in an easterly direction along the northern boundary of the Fort Lewis Military Reservation to its intersection with Pacific Avenue, then proceeding in a southerly direction along Pacific Avenue to its intersection with National Park Highway, then proceeding in a southeasterly direction along National Park Highway to its intersection with 224th Street, East, then proceeding in an easterly direction along 244th Street, East, to its intersection with Meridian Street, South, then proceeding in a northerly direction along Meridian Street to the northern boundary of Pierce County, then proceeding in a westerly direction along the northern boundary of Pierce County to its intersection with Puget Sound, then proceeding in a generally southwesterly direction along the banks of the East Passage of Puget Sound, Commencement Bay, and The Narrows to the point of intersection with the westernmost city limits of Tacoma, including all points and places on the southern boundary of the Juan de Fuca Strait from the eastern port limits of Neah Bay to the western port limits of Port Townsend, all points and places on the western boundary of Puget Sound, including Hood Canal, from the port limits of Port Townsend to the northern port limits of Olympia, all points and places on the southern boundary of Puget Sound from the port limits of Olympia to the western port limits of Tacoma, and all points and places on the eastern boundary of Puget Sound and contiguous waters from the port limits of Tacoma north to the southern port limits of Bellingham, all in the State of Washington.

Regulatory Flexibility Act and Executive Order 12866

Although Customs solicited public comments on this port extension, no notice of proposed rulemaking was required pursuant to 5 U.S.C. 553 because the port extension relates to agency management and organization. Accordingly, this document is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*). Agency organization matters such as this port extension are exempt from consideration under Executive Order 12866.

Drafting Information: The principal author of this document was Janet L. Johnson, Regulations Branch. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Exports, Imports, Organization and functions (Government agencies).

Amendments to the Regulations

Accordingly, Part 101 of the Customs Regulations is amended as set forth below:

PART 101—GENERAL PROVISIONS

1. The general authority citation for Part 101 and the specific authority citation for § 101.3 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1623, 1624.

Sections 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b;

* * * * *

§ 101.3 [Amended]

2. Section 101.3(b)(1) is amended by removing the reference ''T. D. 83–146'' in the ''Limits of port'' column adjacent to the entry of Puget Sound in the ''Ports of entry'' column under the state of Washington and by adding the reference ''T. D. 96–63'' in its place.

Approved: July 29, 1996.

George J. Weise,

Commissioner of Customs.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–21487 Filed 8–22–96; 8:45 am]

BILLING CODE 4820–02–P

INTERNATIONAL TRADE COMMISSION

19 CFR Part 210

Procedures for Investigations and Related Proceedings Concerning Unfair Practices in Import Trade

AGENCY: U.S. International Trade Commission.

ACTION: Final rule.

SUMMARY: The Commission hereby adopts certain interim rules as final rules of practice and procedure for investigations and related proceedings under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). The Commission also revises the interim rule concerning investigation target dates, and adopts that rule as a final rule. This change is made, in response to public comment, so that any decision that results in a target date beyond fifteen months will be by initial determination. The Commission further revises the final rule concerning modification or rescission of exclusion orders, cease and desist orders, and consent orders to eliminate the publication of Federal Register notices that are not required by law, to eliminate unnecessary publication costs.

DATES: The effective date of these final rules is September 23, 1996. These final rules will apply to all section 337 investigations and proceedings instituted after September 23, 1996, as well as to complaints requesting the institution of a section 337 investigation and petitions for modification or rescission of exclusion orders, cease and desist orders, and consent orders filed after September 23, 1996.

FOR FURTHER INFORMATION CONTACT: Sidney Harris or Paul J. Luckern, Office of Administrative Law Judges, U.S. International Trade Commission, telephone (202) 205–2692 or (202) 205–2694. Hearing impaired individuals can obtain information on the final rules by contacting the Commission's TDD terminal at (202) 205–1810.

SUPPLEMENTARY INFORMATION:

Rulemaking Analysis

The final rules proposed in this notice do not meet the criteria enumerated in

section 3(f) of Executive Order 12866,[1] and therefore do not constitute a significant regulatory action for purposes of that Executive Order.

In accordance with the Regulatory Flexibility Act,[2] the Commission hereby certifies [3] that the revised rules set forth in this notice are not likely to have a significant economic impact on a substantial number of small business entities. The Commission notes that most section 337 complainants are not small businesses. Moreover, proposed final rule 210.51(a) merely requires any extension of a target date beyond 15 months to be by initial determination, and proposed final rule 210.76(b) merely ceases publication of certain section 337 Federal Register notices that are not required by law.[4] In any event, the Regulatory Flexibility Act is inapplicable to this rulemaking, because it is not one for which a notice of proposed rulemaking was required under 5 U.S.C. 553(b) or another statute.[5]

Background

Interim rules

On December 30, 1994, the Commission published interim rules implementing the statutory amendments to section 337 effected by the Uruguay Round Agreements Act (URAA) (59 FR 67622, Dec. 30, 1994). Public comment was invited during a 90-day period ending March 30, 1995. The Commission received comments from The International Trade Commission Trial Lawyers Assoc. (ITCTLA), Texas Instruments (TI), Minnesota Mining and Manufacturing Co. (3M), Mr. Gilbert B. Kaplan of the law firm of Hale and Dorr (Kaplan), the Government of Canada (Canada) and the Japan Machinery Exporters' Association (JMEA). The Commission took those comments into account before promulgating these final rules. As these final rules are, with one exception, identical to the interim rules on which public comment was invited and received, no further notice and comment period is found necessary. See e.g. American Transfer & Storage Co. v. *I.C.C.*, 719 F.2d 1283 (5th Cir. 1983); *Methodist Hosp. of Sacramento* v. *Shalala*, 38 F.3d 1225 (D.C. Cir. 1994); *City of Stoughton, Wis.* v. *EPA*, 858 F.2d 747 (D.C. Cir. 1988). Each comment on the interim rules is summarized and the Commission's responses are provided in the section-by-section analysis of the final rules. Only section 210.51(a) is changed from the interim rules. In response to public comment, final rule 210.51(a) now provides that any extension of an investigation target date beyond 15 months shall be by initial determination, subject to discretionary review by the Commission. Final rule 210.76(b)

Final rule 210.76(b) is being revised to eliminate the provision stating that the Commission will institute proceedings to modify or rescind a remedial order or a consent order by publishing a notice in the Federal Register. This change is being made to increase the efficiency and economy of the section 337 process by eliminating unnecessary publication costs, as recommended by the Commission's Inspector General. See generally Audit Report No. IG–03–94, *Review of Ways to Increase the Economy and Efficiency of the Process for Conducting Section 337 Investigations,* at pages 2–4 and 8 (Aug. 19, 1994).

Last year, the Commission conducted a separate rulemaking to eliminate provisions of 19 CFR Part 210 requiring the publication of Federal Register notices that are not required by law. The proposed revision of final rule 210.76(b) was inadvertently omitted from the notice of proposed rulemaking published at 60 FR 16082 (Mar. 29, 1995). The notice of final rulemaking published at 60 FR 53117 (Oct. 12, 1995) acknowledged that omission. That notice also stated that the Federal Register publication requirement of final rule 210.76(b) had been suspended in Administrative Orders 95–12 (Mar. 21, 1995) and 95–18 (Oct. 4, 1995) and that a proposed revision of final rule 210.76(b) to delete the Federal Register notice requirement would be published for public comment at a later date. See 60 FR at 53119.

The Commission has since decided, however, that the costs and the administrative burden of utilizing the notice and public comment procedure to revise final rule 210.76(b) outweigh any potential benefits. Significant amounts of staff time and resources are consumed in the preparation of notices for publication. In addition, publication fees are not nominal. Though discounts are available, the fee for publishing a notice in the Federal Register can be as high as $125 per column (with no proration for partial columns) and $375 per page. The Commission also must bear the cost of reproducing the notice for distribution to the public through the Office of the Secretary and other sources, as well as the cost of mailing copies to various bar groups, other Federal agencies, and other interested persons or organizations.

The notice and comment procedure of 5 U.S.C. 553(b) is not only costly, it also lengthens the time it takes for the Commission to effect the desired rule change. After a notice of proposed rulemaking is published in the Federal Register, interested persons must be given adequate time to review the proposed rules and determine whether they wish to submit comments, as well as adequate time to prepare and file the comments. The Commission must then review those comments before making a final decision on the content of the revised rule. (Moreover, after the Commission makes a final decision on content, the revised rule generally cannot go into effect for at least 30 days after a notice of final rulemaking is published in the Federal Register. See 5 U.S.C. § 553(d).)

Judging by the response to the notice of proposed rulemaking published at 60 FR 16082, it seems unlikely that a notice of proposed rulemaking concerning the revision of final rule 210.76(b) would generate much public comment. In addition to publishing that notice in the Federal Register, the Commission mailed that notice to bar groups, Federal agencies, and other interested persons or organizations that routinely receive such notices. Only one bar group and one agency commented on the proposed revision of the part 210 rules to eliminate the publication of Federal Register notices that are not required by law.

Even though the aforementioned notice of proposed rulemaking did not set forth a proposed revision of final rule 210.76(b), the ITCTLA urged the Commission not to suspend or eliminate the Federal Register notice requirement of that rule. The ITCTLA noted that the Federal Register is a reliable and readily accessible data base. The ITCTLA added that Federal Register notices of Commission proceedings to modify or rescind a remedial order or a consent order fill a valuable due process role by alerting interested persons to a potential disturbance of the status quo—which enables them to take whatever action they deem necessary to protect their interests.

The Commission considered the ITCTLA comments, but has decided that final rule 210.76(b) must be revised for the same reasons that the relevant provision of that rule was suspended and that other part 210 rules were revised last year to eliminate Federal Register notice requirements. (See 60 FR at 53118.) Those reasons include (1) the need to reduce unnecessary spending, (2) the fact that section 337 notices are available from various sources, (3) the absence of any indication that

[1] 58 FR 51735, Oct. 4, 1993.

[2] 5 U.S.C. 601 note.

[3] Pursuant to 5 U.S.C. 605(b).

[4] See 60 FR 53119 (Oct. 12, 1995).

[5] See 5 U.S.C. 603(a).

suspension of the Federal Register notice requirement imposed by final rule 210.76(b) has caused significant problems for parties, the Commission's staff, interested members of the public, or other Federal agencies, and (4) the absence of any indication that revising that rule by deleting the publication requirement is likely to cause such problems in the future.

Interested persons who wish to contest the revision of final rule 210.76(b) can petition the Commission to have the revised rule amended or repealed, pursuant to 5 U.S.C. 553(e) and 19 CFR 201.4(b).

The Federal Register publication requirement of final rule 210.76(b) is an agency rule of practice and procedure. Hence, the proposed revision of final rule 210.76(b) to eliminate that requirement need not be published in a notice of proposed rulemaking that solicits public comment. See 5 U.S.C. 553(b).

Section-By-Section Analysis of the Final Rules

Many of the final rules discussed in this notice are identical to the correspondingly numbered interim rules published on December 30, 1994. No comment was received on many of the interim rules, and the Commission found no reason to change those interim rules on its own before adopting them as final rules. Thus, the preamble to those final rules is as set forth in the ''Section-By-Section Analysis of the Interim Rules'' found at 50 FR 67624–67626 (Dec. 30, 1994) (hereinafter referred to as ''preamble'').[6]

The Commission did receive comments on certain interim rules, and those comments and the views of the Commission are summarized below. The commentary in the December 30, 1994, notice is considered part of the preamble to those final rules, to the extent that such commentary is not inconsistent with the discussion below.

Subpart C—Pleadings

Section 210.14

The interim rules added a new paragraph (e) to section 210.14 to implement the amendment to Section 337(c) of the Tariff Act with regard to counterclaims. Interim rule 210.14(e) requires that counterclaims be filed not later than 10 business days before the commencement of the evidentiary hearing.

The ITCTLA, TI, 3M and Kaplan commented that the preamble to interim rule 210.14(e) suggests that the deadline for counterclaims is being set at 10 business days before the evidentiary hearing to permit respondents to use discovery mechanisms to ''identify potential counterclaims'' and that because counterclaims which a respondent can raise also include permissive counterclaims (i.e., claims unrelated to the complaint), the preamble can be construed to support discovery on unrelated matters to determine whether they constitute potential counterclaims.

Canada and the JMEA objected to the changes made by the URAA regarding counterclaims as insufficient to meet U.S. obligations under the General Agreement on Tariffs and Trade (GATT). Canada and the JMEA further commented on the inability of a respondent to raise a counterclaim at the Commission, at least to the extent that the subject matter of the counterclaim falls within the jurisdiction of the Commission. The JMEA proposed that the Commission draft rules to provide that if a respondent in a first section 337 investigation files a complaint with the Commission alleging violation of section 337 in a second investigation, the second investigation can be joined to the first investigation.

The requirement that counterclaims be filed not later than ten business days before the commencement of the evidentiary hearing was included to provide a respondent adequate time to identify potential counterclaims while avoiding the distraction that might occur if counterclaims could be filed during (or after) the evidentiary hearing. Discovery at the Commission is not for the purpose of generating a counterclaim and the scope of discovery is not expanded by the new counterclaim provision beyond what was previously allowed in Commission investigations.

The comments of Canada and the JMEA regarding interim rule 210.14(e) are based on their perceptions of deficiencies in the URAA. As such, the Commission does not find it appropriate to incorporate changes based on these comments into its final rules. Moreover, the joinder of two section 337 investigations, as proposed by the JMEA, may be sought by motion under section 210.15. The Commission notes that such a motion for joinder was, in fact, granted in Certain Precision Resistor Chips, 337–TA–63/65, Order No. 2 (May, 1979).

In view of the foregoing, the Commission has determined that no changes to interim rule 210.14 are warranted.

Subpart D—Motions

Section 210.23

Interim rule 210.23 eliminates the provision allowing the Commission to suspend an investigation because of a proceeding in a court or agency of the United States involving similar subject matter, except for possible antidumping or countervailing duty matters referred to the Department of Commerce by the Commission.

Canada maintains that interim rule 210.23 may exacerbate discriminatory features of section 337 identified by the GATT Panel Report in Aramid Fiber, BISD 36S/345, Adopted 11/7/89, pertaining to dual proceedings.

It is important to bear in mind the reason underlying the changes to section 210.23. Interim rule 210.23 reflects the amendments to section 337(b)(1) that eliminated statutory deadlines. Administrative law judges and the Commission retain the inherent authority to suspend an investigation, based on a parallel proceeding, although it is expected that this authority will be used sparingly. Moreover, the addition of 28 U.S.C. 1659 now provides respondents with the ability to obtain a stay of a parallel District Court proceeding.

In view of the foregoing, the Commission has determined that no changes to interim rule 210.23 are warranted.

Subpart G—Determinations and Actions Taken

Sections 210.42 and 210.51

Interim rule 210.51 requires the administrative law judge, within 45 days of institution of an investigation, to set a target date for completion of that investigation. Any decision to set a target date of 15 months or more is by initial determination, subject to discretionary review by the Commission. Interim rule 210.42(c) provides, in relevant part, that motions to set a target date exceeding 15 months from the date of institution, pursuant to interim rule 210.51(a), are granted by initial determination.

The ITCTLA, 3M, TI and Kaplan commented that the Commission should be directly responsible for setting the target dates, and that this decision should not be delegated to the administrative law judges.

The JMEA commented that the rules should not be administered in a manner that effectively imposes a time limit on the administrative law judge which the JMEA maintained would be the case if

[6] The Commission received no comments on the following interim rules: 210.3–210.5; 210.16; 210.21–210.22; 210.24; 210.39; 210.41; 210.43; 210.49–210.50.

the discretion of the judge were limited to establishing target dates of 15 months or less. 3M and Kaplan commented that the choice of 15 months as the time that triggers Commission review seems to give a degree of approval to target dates exceeding 12 months, and that Commission review should be triggered by any target date that exceeds 12 months.

The Commission finds that it is appropriate for the administrative law judge to set all target dates. Allowing the administrative law judge to set target dates within a 12- to 15-month period of time, without Commission review, greatly simplifies judicial management of investigations. It is expected that the administrative law judges will abide by the intent of Congress and the Commission, and conclude most investigations within the traditional period of 12 months or less.

The ITCTLA commented that interim rule 210.51, when read in conjunction with the Commission's review authority set forth in § 210.42(h)(3), violates the amended statute's requirement that the Commission shall establish a target date within 45 days after an investigation is instituted with respect to an initial determination setting a target date of more than 15 months. The ITCTLA commented that, for example, should an administrative law judge, 45 days after institution, set a target date of 18 months, the target date will not become the determination of the Commission until 30 day later, or a total of 75 days, and should the Commission choose to review the initial determination the period could be extended even further.

The ITCTLA further commented that interim rule 210.51 should be amended such that any subsequent modification by the administrative law judge to the target date, based on good cause, should be in the form of an initial determination subject to review by the Commission in every instance.

The Commission recognizes that section 337(b)(1) requires that the Commission ''within 45 days after an investigation is initiated, establish a target date for its final determination.'' Under interim rule 210.51, any decision by the administrative law judge to set a target date of 15 months or less is not subject to review, and thus will be final within 45 days after institution of the investigation. It is expected that target dates will rarely exceed 15 months. In the rare case where a target date in the first instance is set in excess of 15 months, the initial determination and any subsequent review by the Commission will be completed within 45 days of institution, as required by section 337(b)(1). Thus, no modification of interim rule 210.51 is found necessary. The Commission, however, has modified interim rule 210.51, such that, under final rule 210.51(a), any extension that would result in a target date beyond 15 months from institution will be by initial determination, and subject to discretionary review by the Commission.

Subpart H—Temporary Relief

Sections 210.52 and 210.70

These rules provide for the posting and forfeiture of a complainant's bond when a complainant seeks temporary relief.

Canada commented that the statute and rules make no provision for a bond requirement on a complainant where no temporary relief has been sought, and suggested that provision should be made for the indemnification of the defendant in all situations.

To the extent that Canada's comment is based on its perception of a deficiency in the URAA, the Commission does not consider it appropriate to incorporate changes based on this comment in its rules. Furthermore, the Commission finds no need for such a provision. In cases involving a successful motion for temporary relief, articles may only enter or be sold in the United States during the pendency of an investigation upon the posting of a bond. In cases that do not involve a motion for temporary relief, by contrast, respondents do not require any indemnification, because respondents' articles are not subject to exclusion until a final determination of violation by the Commission.

Subpart I—Enforcement Procedures and Advisory Opinions

Section 210.76

Paragraph (b) of final rule 210.76 requires that the Commission publish a Federal Register notice in order to institute a proceeding to modify or rescind the exclusion order, cease and desist order, or consent order. The Commission proposes to revise paragraph (b) by eliminating the publication requirement and allowing the Commission to institute such proceedings simply by issuing a notice.

Miscellaneous

The JMEA maintained that in order to comply with the spirit of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the Commission should clarify that (1) the domestic industry requirement under section 337 cannot be satisfied by an individual inventor pursuing his or her personal monetary interest by enforcing his or her paper patent, and (2) that section 337 is not a vehicle for pursuing such personal interest. Those comments, however, relate to questions of statutory interpretation, dealing with the substance of section 337, and do not implicate any Commission procedural rule.

List of Subjects in 19 CFR Part 210

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

For the reasons set forth in the preamble, 19 CFR Part 210 is amended as set forth below.

PART 210—ADJUDICATION AND ENFORCEMENT

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

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

2. The interim rule amendments to §§ 210.3, 210.4, 210.5, 210.14, 210.16, 210.21, 210.22, 210.23, 210.24, 210.39, 210.42, 210.43, 210.49, 210.50, 210.52 and 210.70, published on December 30, 1994 (59 FR 67622) are adopted as final rules without change.

Note: § 210.21(d) has been further amended by a rule published on Oct. 12, 1995 (60 FR 53120).

3. The interim rule amending § 210.51 (b) and (c) published on December 30, 1994 (59 FR 67622) is adopted as a final rule and paragraph (a) is revised to read as follows:

§ 210.51 Period for concluding investigation.

(a) *Permanent relief.* Within 45 days after institution of the investigation, the administrative law judge shall issue an order setting a target date for completion of the investigation. If the target date does not exceed 15 months from the date of institution of the investigation, the order of the administrative law judge shall be final and not subject to interlocutory review. If the target date exceeds 15 months, the order of the administrative law judge shall constitute an initial determination. After the target date has been set, it can be modified by the administrative law judge for good cause shown before the investigation is certified to the Commission or by the Commission after the investigation is certified to the Commission. Any extension of the target date beyond 15 months, before the investigation is certified to the Commission, shall be by initial determination.

* * * * *

4. Paragraph (b) of § 210.76 is revised to read as follows:

§ 210.76 Modification or rescission of exclusion orders, cease and desist orders, and consent orders.

* * * * *

(b) *Commission action upon receipt of petition.* The Commission may thereafter institute a proceeding to modify or rescind the exclusion order, cease and desist order, or consent order by issuing a notice. The Commission may hold a public hearing and afford interested persons the opportunity to appear and be heard. After consideration of the petition, any responses thereto, and any information placed on the record at a public hearing or otherwise, the Commission shall take such action as it deems appropriate. The Commission may delegate any hearing under this section to the chief administrative law judge for designation of a presiding administrative law judge, who shall certify a recommended determination to the Commission.

By Order of the Commission.
Issued: August 19, 1996.

Donna R. Koehnke,

Secretary.

[FR Doc. 96–21522 Filed 8–22–96; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95P–0003]

Food Labeling: Health Claims; Sugar Alcohols and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use, on food labels and in food labeling, of health claims on the association between sugar alcohols and the nonpromotion of dental caries. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts to support the relationship between sugar alcohols (i.e., xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, hydrogenated starch hydrolysates (HSH), hydrogenated glucose syrups (HGS), or a combination of sugar alcohols) and the nonpromotion of dental caries. Therefore, FDA has concluded that claims on foods relating sugar alcohols to the nonpromotion of dental caries are justified. FDA is announcing these actions in response to a petition filed by the National Association of Chewing Gum Manufacturers, Inc., and an ad hoc working group of sugar alcohol manufacturers (hereinafter referred to as the petitioners).

DATES: Effective January 1, 1998. 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 101.80(c)(2)(ii)(C), effective January 1, 1998.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 20, 1995 (60 FR 37507), the agency proposed to authorize the use, on food labels and in food labeling, of health claims on the association between sugar alcohols and the nonpromotion of dental caries. In addition, FDA proposed to exempt sugar alcohol-containing foods from the requirement in § 101.14(e)(6) (21 CFR 101.14(e)(6)) of the health claims general requirements regulation concerning disqualification criteria. Section 101.14(e)(6) provides that, except for dietary supplements or where provided for in other regulations in part 101 (21 CFR part 101), subpart E, to be eligible to bear a health claim, a food must contain 10 percent or more of the Reference Daily Intake (RDI) or the Daily Reference Value (DRV) for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before there is any nutrient addition.

The proposed rule was issued in response to a petition filed under section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) shall promulgate regulations authorizing health claims only if he or she determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (see also § 101.14(c)). FDA considered the relevant scientific studies and data presented in the petition as part of its review of the scientific literature on sugar alcohols and dental caries. The agency summarized this evidence in the proposed rule (60 FR 37507).

The proposed rule included qualifying and disqualifying criteria for the purpose of identifying foods eligible to bear a health claim. The proposal also specified mandatory content and label information for health claims statements and provided model health claims. In its review of sugar alcohols eligibility for a health claim under § 101.14(b), FDA discussed potential safety issues relating to sugar alcohols and the petitioners' position that the use of sugar alcohols is safe and lawful. The agency also discussed the potential issue that some sugar alcohol-containing foods may contain other ingredients, such as refined flour, that may be cariogenic. Consequently, the agency proposed to require that sugar alcohol-containing foods not lower plaque pH below 5.7, as determined by appropriate in vivo tests. FDA requested written comments on the proposed rule, including comments on the agency's tentative conclusion that the petitioners had satisfied the requirements regarding the safe and lawful use of sugar alcohols that are the subject of the health claim and comments on the proposal to establish a minimum plaque pH test for sugar alcohol-containing foods.

II. Summary of Comments and the Agency's Responses

In response to the proposal, the agency received approximately 20 letters, each containing one or more comments, from professional organizations, industry, trade associations, and health care professionals. Comments that were not relevant to the sugar alcohol and dental caries proposed rule, but that addressed broader issues pertaining to health claims in general, are not discussed in the sections of this document that follow.A number of comments were received that dealt generally with the questions of whether health claims need to state that the disease or health-related condition is multifactorial, and whether the whole claim needs to appear in one place. These issues of broad applicability to health claims are being considered in the rulemaking entitled ''Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims'' (60 FR