manure and litter from the infected premises must be moved to the composting site at the same time;

(5) Following the composting process, the composted manure or litter remains undisturbed for an additional 15 days before movement;

(6) After this 15-day period, all of the composted manure or litter from the infected site is removed at the same time;

(7) The resulting compost must be transported either in a previously unused container or in a container that has been cleaned and disinfected, since last being used, in accordance with part 71 of this chapter;

(8) The vehicle in which the resulting compost is to be transported has been cleaned and disinfected, since last being used, in accordance with part 71 of this chapter; and

(9) Copies of the permit accompanying the compost derived from the manure and the litter are submitted so that a copy is received by the State animal health official and the veterinarian in charge for the State of destination within 72 hours of arrival of the compost at the destination listed on the permit.

■ 7. Section 82.8 is amended as follows:

■ a. In paragraph (a)(2), by removing the citation ''7 CFR part 59'' and adding the citation ''9 CFR part 590'' in its place.

■ b. By revising paragraph (a)(3) to read as set forth below.

§ 82.8 Interstate movement of eggs, other than hatching eggs, from a quarantined area.

(a) * * *

(3) The establishment that processes the eggs, other than hatching eggs, for sale establishes procedures adequate to ensure that the eggs are free of END, including:

(i) The establishment separates processing and layer facilities, the incoming and outgoing eggs at the establishment, and any flocks that may reside at the establishment;

(ii) The establishment implements controls to ensure that trucks, shipping companies, or other visitors do not expose the processing plant to END;

(iii) Equipment used in the establishment is cleaned and disinfected in accordance with part 71 of this chapter at intervals determined by the Administrator to ensure that the equipment cannot transmit END to the eggs, other than hatching eggs, being processed; and

(iv) The eggs are packed either in previously unused flats or cases, or in used plastic flats that were cleaned or disinfected since last being used, in accordance with part 71 of this chapter;

* * * * *

■ 8. Section 82.9 is amended as follows:

■ a. In paragraph (b), by removing the word ''and'' at the end of the paragraph.

■ b. By redesignating paragraph (c) as paragraph (d).

■ c. By adding a new paragraph (c) to read as set forth below.

§ 82.9 Interstate movement of hatching eggs from a quarantined area.

* * * * *

(c) The hatching eggs have been kept in accordance with the sanitation practices specified in § 147.22 and § 147.25 of the National Poultry Improvement Plan; and

* * * * *

■ 9. Section 82.14 is amended as follows:

■ a. In paragraph (c)(2), in the introductory text, by revising the second sentence to read as set forth below.

■ b. In paragraph (e)(2), by removing the first sentence and by adding two new sentences in its place to read as set forth below.

■ c. By adding a new paragraph (i) to read as set forth below.

§ 82.14 Removal of quarantine.

* * * * *

(c) * * *

(2) * * * The birds and poultry must be composted according to the following instructions or according to another procedure approved by the Administrator as being adequate to prevent the dissemination of END:

* * * * *

(e) * * *

(2) *Composting.* If the manure and litter is composted, the manure and litter must be composted in the quarantined area. The manure and litter must be composted according to the following method, or according to another procedure approved by the Administrator as being adequate to prevent the dissemination of END: Place the manure and litter in rows 3 to 5 feet high and 5 to 10 feet at the base. * * *

* * * * *

(i) After the other conditions of this section are fulfilled, an area will not be released from quarantine until followup surveillance over a period of time determined by the Administrator indicates END is not present in the quarantined area.

* * * * *

Done in Washington, DC, this 20th day of May 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–11741 Filed 5–23–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2006–P–0404] (Formerly Docket No. 2006P–0487)

Food Labeling: Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting as a final rule, without change, the provisions of the interim final rule that amended the regulation authorizing a health claim on noncariogenic carbohydrate sweeteners and dental caries, i.e., tooth decay, to include isomaltulose as a substance eligible for the health claim. FDA is taking this action to complete the rulemaking initiated with the interim final rule.

DATES: This rule is effective May 27, 2008.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 17, 2007 (72 FR 52783), FDA published an interim final rule to amend the regulation in part 101 (21 CFR part 101) that authorizes a health claim on the relationship between noncariogenic carbohydrate sweeteners and dental caries (§ 101.80) to include the noncariogenic sugar isomaltulose. Under section 403(r)(3)(B)(i) and section 403(r)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i) and 343(r)(7)), FDA issued this interim final rule in response to a petition filed under section 403(r)(4) of the act. Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (and, by delegation, FDA) shall issue a

regulation authorizing a health claim 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)). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a health claim petition. Section 403(r)(7) of the act permits FDA to make a proposed regulation issued under section 403(r) effective upon publication pending consideration of public comment and publication of a final regulation if the agency determines that such action is necessary for public health reasons.

On August 31, 2006, Cargill, Inc. (petitioner), submitted a health claim petition to FDA requesting that the agency amend the ''dietary noncariogenic carbohydrate sweeteners and dental caries'' claim at § 101.80 to authorize a noncariogenic dental health claim for isomaltulose. FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on December 8, 2006. The petitioner requested that FDA grant an interim final rule by which foods containing isomaltulose could bear the health claim prior to publication of the final rule. FDA and the petitioner mutually agreed to extend the deadline for the agency's decision on the petition to September 5, 2007.

As part of its review of the scientific literature on isomaltulose and dental caries, FDA considered the scientific evidence presented in the petition as well as information previously considered by the agency on the etiology of dental caries and the effects of slowly fermentable carbohydrates. The agency summarized this evidence in the interim final rule (72 FR 52783 at 52784 to 52786). Based on the available evidence, FDA concluded that isomaltulose, like other noncariogenic carbohydrate sweeteners listed in § 101.80(c)(2)(ii), does not promote dental caries. Consequently, FDA amended § 101.80(c)(2)(ii) to broaden the health claim to include isomaltulose as an additional substance eligible for the health claim.

II. Summary of Comments and the Agency's Response

FDA solicited comments on the interim final rule. The comment period closed on December 3, 2007. The agency received four letters of response, three from consumers and one from a manufacturer. The manufacturer supported the interim rule. Two of the consumers' comments addressed issues that are outside the scope of this rulemaking and will not be addressed here. The remaining comment suggested that there had been insufficient testing to demonstrate the safety of isomaltulose, but did not provide any information or analysis to support revision of the agency's conclusion.

Given the absence of contrary evidence on the agency's decisions announced in the interim final rule, FDA is adopting as a final rule, without change, the interim final rule that amended § 101.80 to include isomaltulose as a substance eligible for the dental caries health claim.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule allows new voluntary behavior and imposes no additional restrictions on current practices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement which includes an assessment of anticipated costs and benefits before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127,000,000, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any one-year expenditure that would meet or exceed this amount.

FDA received no comments relevant to economic impact. The costs and benefits of available regulatory alternatives analyzed in the interim final rule (72 FR 52783 at 52787 to 52788) are adopted without change in this final rule. By now affirming that interim final rule, FDA has not imposed any new requirements. Therefore, there are no additional costs and benefits associated with this final rule.

IV. Environmental Impact

The agency has determined under 21 CFR 25.32(p) 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.

V. Paperwork Reduction Act

FDA concludes that the labeling provisions of this final rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the food labeling health claim on the association between consumption of isomaltulose and the nonpromotion of dental caries is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule will have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(5) of the act provides that:

* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—* * *(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not

identical to the requirement of section 403(r) * * *

On September 17, 2007, FDA published an interim final rule which imposed requirements under section 403(r) of the act. This final rule affirms the September 17, 2007, amendment to the existing food labeling regulations to add isomaltulose to the authorized health claim for noncariogenic carbohydrate sweeteners and dental caries. Although this rule has a preemptive effect in that it precludes States from issuing any health claim labeling requirements for isomaltulose and the nonpromotion of dental caries that are not identical to those required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both State legislative requirements and State common law duties. *Riegel v. Medtronic*, 128 S. Ct. 999 (2008).

FDA believes that the preemptive effect of this final rule is consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' On August 1, 2007, FDA's Division of Federal and State Relations provided notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors, as well as FDA field personnel, of FDA's intent to amend the health claim regulation authorizing health claims for noncariogenic carbohydrate sweeteners and dental caries (§ 101.80). FDA received no comments from any States in response to this notice.

In addition, the agency sought input from all stakeholders through publication of the interim final rule in the **Federal Register** on September 17, 2007 (72 FR 52783). FDA received no comments from any States on the interim final rule.

In conclusion, the agency believes that it has complied with all of the applicable requirements of Executive Order 13132 and has determined that the preemptive effects of this rule are consistent with the Executive order.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and Recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ Accordingly, the interim final rule amending § 101.80 that was published in the **Federal Register** of September 17, 2007 (72 FR 52783), is adopted as a final rule without change.

Dated: May 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–11802 Filed 5–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9400]

RIN 1545–BG97

Treatment of Property Used To Acquire Parent Stock in Certain Triangular Reorganizations Involving Foreign Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations under section 367(b) of the Internal Revenue Code (Code). The final regulations revise an existing final regulation and add a cross-reference. The temporary regulations implement the rules described in Notice 2006–85 and Notice 2007–48. The regulations affect corporations engaged in certain triangular reorganizations involving one or more foreign corporations. The text of the temporary regulations serves as the text of the proposed regulations (REG–136020–07) set forth in the notice of proposed rulemaking on this subject published in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective May 27, 2008.

Applicability Dates: For dates of applicability, see § 1.367(a)–3T(b)(2)(i)(C) and 1.367(b)–14T(e).

FOR FURTHER INFORMATION CONTACT: Daniel McCall, (202) 622–3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On September 22, 2006, the IRS and Treasury Department issued Notice 2006–85 (2006–41 IRB 677), which announced that regulations would be issued under section 367(b) to address certain triangular reorganizations under section 368(a) involving one or more foreign corporations. On May 31, 2007, the IRS and Treasury Department issued Notice 2007–48 (2007–25 IRB 1428), which amplified Notice 2006–85 and announced that additional regulations would be issued under section 367(b). Each notice describes transactions the IRS and Treasury Department believe raise significant policy concerns.

Notice 2006–85 describes triangular reorganizations in which a subsidiary (S) purchases stock of its parent corporation (P) from P in exchange for property, and then exchanges the P stock for the stock or assets of a target corporation (T), but only if P or S (or both) is foreign. Notice 2006–85 announced that regulations to be issued under section 367(b) would make adjustments that would have the effect of a distribution of property from S to P under section 301 (deemed distribution). Notice 2006–85 further announced that regulations would address similar transactions where S acquires the P stock from a related party that purchased the P stock in a related transaction.

Notice 2007–48 describes transactions in which S purchases all or a portion of the P stock exchanged in the reorganization from a person other than P (such as from public shareholders on the open market). Notice 2007–48 announced that regulations to be issued under section 367(b) would also make adjustments that would have the effect of a distribution of property from S to P (under section 301) followed by a deemed contribution of such property by P to S. Notice 2007–48 further announced that the regulations would take into account the earnings and profits of other corporations, as appropriate, if a principal purpose of creating, organizing, or funding S is to avoid the adjustments to be made by the regulations.

These temporary regulations set forth the regulations described in Notices 2006–85 and 2007–48. The existing final regulations under § 1.367(b)–13 are revised to conform the definitions of the terms P, S, and T in those regulations to the definitions of such terms in these temporary regulations. The existing final regulations under § 1.367(b)–2 are revised to clarify that the definition of earnings and profits in § 1.367(b)–2(l)(8) applies only for purposes of §§ 1.367(b)–7 and 1.367(b)–9.