4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 150

[Docket No. FDA-1997-P-0007 (formerly Docket No. 1997P-0142)]

Artificially Sweetened Fruit Jelly and Artificially Sweetened Fruit Preserves and Jams; Revocation of Standards of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is revoking the standards of identity for artificially sweetened jelly, preserves, and jams. We are taking this action primarily in response to a citizen petition submitted by the International Jelly and Preserve Association (IJPA). We also are taking this action because these standards are obsolete and unnecessary in light of our regulations for foods named by use of a nutrient content claim and a standardized term. This action will promote honesty and fair dealing in the interest of consumers.

DATES: The final rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Terri Wenger, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

For more than 50 years, we have maintained standards of identity for fruit jelly (jelly) (§ 150.140 (21 CFR 150.140)) and fruit preserves and jams (preserves and jams) (§ 150.160). The standards establish the common or usual name for these products and provide that these products may contain nutritive sweeteners (e.g., sugar). In 1959, we added new standards of identity for artificially sweetened fruit jelly (artificially sweetened jelly) (§ 150.141) and artificially sweetened fruit preserves and jams (artificially sweetened preserves and jams) (§ 150.161) (24 FR 8896; October 31, 1959) that permit the use of non-nutritive sweeteners (e.g., saccharin). Notably, §§ 150.141 and 150.161 limit the types of non-nutritive sweeteners that can be used in products that are governed by those standards of identity. Under §§ 150.141 and 150.161, such products may only use saccharin, sodium saccharin, calcium saccharin, or any combination thereof, and may not use newer forms of non-nutritive sweeteners that have been developed since the standard of identity regulations were issued.

The Nutrition Labeling and Education Act (NLEA) of 1990 amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to provide for a number of fundamental changes in food labeling, leading to a new regulatory framework for the naming of foods that do not fully comply with the relevant standards of identity. In response to NLEA, we established in part 101 (21 CFR part 101), among other things, definitions for specific nutrient content claims using terms such as "free", "low", "light" or "lite", and "less", and provided for their use in food labeling (58 FR 2302; January 6, 1993). We also prescribed, in § 130.10 (21 CFR 130.10), a general definition and standard of identity for foods named by a nutrient content claim defined in part 101, such as "low calorie" or "sugar free", in conjunction with a traditional standardized food term (58 FR 2431; January 6, 1993). A nutrient content claim applied to the standardized food "grape jelly", for example, could be "low calorie grape jelly". Section 130.10(d)(1) allows

the addition of safe and suitable ingredients to a food named by use of a nutrient content claim and a standardized term when these ingredients are used to, among other things, add sweetness to ensure that the modified food is not inferior in performance characteristics to the standardized food even if such ingredients are not specifically provided for by the relevant food standard. Thus, under certain circumstances, § 130.10 permits manufacturers to use safe and suitable artificial sweeteners (e.g., sucralose) that are not expressly listed in §§ 150.141 and 150.161 in the manufacture of jelly, fruit preserves, and jams (collectively, "fruit spreads"). Therefore, fruit spread products named with a nutrient content claim (for example, "low calorie grape jelly") may contain newer artificial sweeteners to add sweetness to fruit spread products so that they are not inferior in their sweetness compared to their standardized counterparts (for example, "grape jelly"). Section 130.10 does not require these products to declare the presence of such non-nutritive sweeteners within the name of these foods. We took this action to help consumers in maintaining healthy dietary practices by providing for a modified version of a traditional standardized food to achieve a nutrition goal (e.g., reduction in sugar consumption or calories) and that has a descriptive name that is meaningful to consumers. Section 130.10 does not, however, permit the use of nutrient content claims as part of the name of a food for foods governed by standards of identity that established the phrase "artificially sweetened" as part of the standard of identity. Accordingly, jelly, preserves, and jams, that use saccharin, sodium saccharin, calcium saccharin, or any combination thereof as non-nutritive sweeteners must still include the term "artificially sweetened" in their names and are not permitted to bear a nutrient content claim as part of the name. However, similar products that use newer non-nutritive sweeteners are governed by § 130.10 and are not required to include the term "artificially sweetened" in their names.

In the Federal Register of December 4, 2012, we proposed to revoke the standards of identity for artificially sweetened jelly, preserves, and jam in §§ 150.141 and 150.161 (77 FR 71746). The proposed rule was in response to a citizen petition submitted by the IJPA requesting such a revocation. In issuing the notice of proposed rulemaking, we stated that we found merit in the argument made in IJPA's petition that revoking §§ 150.141 and 150.161 would allow manufacturers to more accurately and consistently describe the attributes of the fruit spreads that currently conform to those regulations. We therefore tentatively concluded that revoking the standards of identity for artificially sweetened jelly, preserves, and jams would promote honesty and fair dealing in the interest of consumers and was thus appropriate under section 401 of the FD&C Act (21 U.S.C. 341). We tentatively reached this conclusion because we found that nutrient content claims such as "low calorie" or "reduced sugar" better characterize the nutritional profile of the affected fruit spreads than does the term "artificially sweetened". Further, we stated that revoking §§ 150.141 and 150.161 would provide manufacturers with the flexibility to use the three non-nutritive sweeteners listed in those standards while also naming their products using FDA-defined nutrient content claims, in accordance with § 130.10. We also noted that other safe and suitable artificial sweeteners that might be developed in the future could be used in these products under § 130.10 without the need to further revise relevant standards of identity, and that the proposed rule was consistent with FDA's proposed general principles for modernizing food standards (70 FR 29214; May 20, 2005).

II. Comments to the Proposed Rule and FDA's Responses

We received 21 comments to the proposed rule. The comments were from trade associations, food companies, and individuals. Two comments were identical, and another comment appeared to have been misdirected because it pertained to blogs. Most of the

comments made general remarks supporting or opposing the rule and did not focus on a particular component of the rule.

Six comments supported the proposed rule. One comment stated that the proposed rule would provide flexibility to industry to use artificial sweeteners and to not use the term "artificially sweetened" in the name of their products. The comment also stated that the proposed rule would provide consistency and uniformity in the labeling of fruit spreads. Several comments stated that §§ 150.141 and 150.161 limit the type of non-nutritive sweeteners, and that enactment of the NLEA and FDA's regulation in § 130.10 allow flexibility. One of the comments also stated that the use of nutrient content claims such as "reduced sugar" in accordance with § 130.10 provides a better way to communicate with consumers to meet their nutritional goals.

In contrast, other comments opposed the proposed rule. Several comments said that the rule would remove transparency that allows consumers to make knowledgeable decisions. Another expressed concern that the non-nutritive sweeteners would not be labeled and that consumers would be cheated. Still others stated that removing the term "artificially sweetened" is deceitful, would allow harmful chemicals to be hidden in food, and would not protect consumers.

The final rule will not result in the declaration of non-nutritive sweeteners being removed from labels and will not result in substances being hidden in food. In accordance with § 101.4(a) (21 CFR 101.4(a)), ingredients (including non-nutritive sweeteners) must be declared by common or usual name on either the principal display panel or the information panel of the label. Thus, for example, the ingredient panel must list any non-nutritive sweeteners, including, for example, the three saccharin products currently subject to §§ 150.141 and 150.161 and any of the

newer non-nutritive sweeteners such as sucralose. What the final rule will do is require any food products currently subject to §§ 150.141 and 150.161 to instead be subject to § 130.10. Although § 130.10 does not require products to declare the presence of non-nutritive sweeteners within the name of these foods (e.g., § 130.10 does not require a jam made with a non-nutritive sweetener to be named "artificially sweetened jam"), it does require foods subject to that provision to be named by use of a nutrient content claim defined in part 101 (e.g., "reduced calorie" or "no sugar added"). Nutrient content claims such as "low calorie" or "no sugar added" better characterize the nutritional profile of the fruit spreads currently subject to §§ 150.141 and 150.161 than does the term "artificially sweetened." The final rule will also allow better comparison to other jams, jellies, and preserves currently modified under the provisions of § 130.10. For example, under current requirements, a jelly that is sweetened with saccharin must be called "artificially sweetened jelly" (in accordance with § 150.141), whereas a similar jelly sweetened with sucralose may be named as "reduced sugar jelly" (in accordance with § 130.10 and provided it meets the requirements for the nutrient content claim "reduced sugar" in § 101.60(c)(5) to distinguish it from the standardized food (jelly in § 150.140). Revoking the standards will provide consistency and uniformity among such products because all fruit spreads sweetened with non-nutritive sweeteners will be subject to the same requirements. For these reasons, the final rule will promote honesty and fair dealing in the interest of consumers consistent with section 401 of the FD&C Act.

As for the comment that artificial sweeteners are "toxic" or "dangerous," that comment does not address the merits of revoking §§ 150.141 and 150.161.

III. Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct 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 Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have concluded, as set forth in this document, that this rule will not generate significant compliance costs, we certify 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 $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Need for This Regulation

We are revoking the standards of identity for artificially sweetened jelly, preserves, and jams because these standards are obsolete and unnecessary. The current standards of identity for artificially sweetened jelly (§ 150.141) and artificially sweetened preserves and jams (§ 150.161) provide that they may be manufactured only with specific, non-nutritive artificial sweeteners: Saccharin, sodium saccharin, calcium saccharin, or any combination thereof. These standards of identity, therefore, do not permit the use of newer, safe, and suitable artificial sweeteners, such as sucralose.

The development of newer artificial sweeteners and the enactment of the NLEA have made the current standards of identity for artificially sweetened jelly, preserves, and jams obsolete. The NLEA and § 130.10 permit the modification of a traditional standardized food to achieve a nutrition goal, such as a reduction in calories. Section 130.10(d)(1) allows the addition of safe and suitable ingredients to a food named by use of a nutrient content claim and a standardized term when these ingredients are used to, among other things, add sweetness to ensure that the modified food is not inferior in performance characteristic to the standardized food, even if such ingredients are not specifically provided for by the relevant food standard.

Standardized jelly and standardized preserves and jams products modified under § 130.10 must use nutrient content claims to communicate the modified standardized product's nutritional profile to consumers. Under § 130.10, nonspecific, safe, and suitable artificial sweeteners other than the three named in §§ 150.141 and 150.161 can be used to make reduced calorie or reduced sugar products labeled with a nutrient content claim that is established in FDA regulations. Revoking the standards of identity means that any product subject to §§ 150.141 and 150.161 will instead be subject to § 130.10. This will allow consumers to better compare any fruit spreads currently covered by §§ 150.141 and 150.161 with other spreads that are named and

modified under the provisions of § 130.10. Revoking the standards also gives manufacturers the flexibility to use the three non-nutritive sweeteners listed in §§ 150.141 and 150.161, while naming their products under § 130.10 using a defined nutrient content claim.

B. Regulatory Options

In assessing our regulatory options, we considered the option of taking no action and the option of implementing this final rule. We conclude that the rule is not an economically significant regulatory action. We are not quantitatively estimating the benefits and costs of the regulatory alternatives to the rule. In the following paragraphs, we qualitatively compare the costs and benefits of the regulatory options to the costs and benefits of the rule.

1. The Option of Taking No Action

By convention, we treat the option of taking no new regulatory action as the baseline for determining the costs and benefits of the other options. Therefore, we associate neither costs nor benefits with this option. The consequences of taking no action are reflected in the costs and benefits associated with taking the action set forth in this rule.

2. The Option of Implementing the Final Rule

By revoking §§ 150.141 and 150.161, products that are currently subject to the requirements of these standards of identity will no longer be required to use the phrase "artificially sweetened" as part of their product name. Furthermore, revoking §§ 150.141 and 150.161 means that these same products will be permitted to bear nutrient content claims along with a standardized term (e.g., "reduced calorie jelly" or "no sugar added jam"), in accordance with § 130.10.

The costs of this rule result from the need to relabel any existing jelly, preserves, and jams that conform with §§ 150.141 and 150.161. Any products currently manufactured in

accordance with the standards in §§ 150.141 and 150.161 will have to be relabeled in order to comply with § 130.10. Our review of supermarket scanner data for the years 2001 through 2010, however, revealed that no such products are currently being sold. Sales for products manufactured and labeled in accordance with §§ 150.141 and 150.161 were last reported in 2002. A memorandum summarizing the results of this scanner data can be found in Reference 1. The data support our conclusion that most manufacturers most likely have discontinued production of jelly, preserves, and jams that must be labeled as "artificially sweetened," presumably because of a perception that the phrase "artificially sweetened" is unattractive to consumers. The data also support our conclusion that it is unlikely that the rule will generate significant compliance costs due to the need to relabel products. In fact, removal of the artificially sweetened standards of identity will allow manufacturers to re-introduce products covered under §§ 150.141 and 150.161 to be sold as products covered by § 130.10. That is, such products would be named by use of a nutrient content claim in conjunction with a standardized term (e.g., "reduced calorie jelly" or "no sugar added jam"), in accordance with § 130.10. Therefore, we conclude that any relabeling compliance costs will be negligible.

We do not classify as anticipated costs of this rule any expenses that firms might voluntarily incur if they choose to change their product formulas or manufacturing practices. Any such costs are not costs that would be required by the rule. Instead, these costs would result from voluntary business decisions made by manufacturers.

We conclude that the principal benefits that will result from the rule derive from increased information and flexibility. Revoking the artificially sweetened standards of identity will provide producers of jelly, preserves, and jams with the flexibility to use saccharin, sodium saccharin, calcium saccharin, or any combination thereof, in their formulations without having to

include the term "artificially sweetened" in their product names. Manufacturers could instead name their products in accordance with approved nutrient content claims, as provided for under § 130.10, thus providing consumers with additional information about the nutritional profile of affected products. Additionally, revoking §§ 150.141 and 150.161 will help consumers compare products covered by the standards with other similar jelly, preserves, and jams manufactured in accordance with § 130.10.

Accordingly, while we do not quantify the costs and benefits of the rule, we conclude that potential benefits will outweigh any potential costs associated with the rule.

C. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because compliance costs, if any, generated by this rule are expected to be negligible, we conclude that this rule will not have a significant economic impact on a substantial number of small entities. The following analysis, in conjunction with the discussion in this document, constitutes our final regulatory flexibility analysis as required by the Regulatory Flexibility Act.

The rule revokes the standards of identity for artificially sweetened jelly, preserves, and jams. The revocation of these artificially sweetened standards of identity gives small fruit spread firms the flexibility to use the three non-nutritive sweeteners listed in §§ 150.141 and 150.161 and to name their products with FDA-defined nutrient content claims in accordance with § 130.10, as is currently done for fruit spread products manufactured with other non-nutritive sweeteners.

We do not classify as costs of this rule any expenses that some small firms might voluntarily incur because they choose to change their product formulas or manufacturing practices. As discussed in this document, any such costs would not be costs required by this rule.

IV. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. 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 FD&C Act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a) of the FD&C 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 any requirement for a food which is the subject of a standard of identity established under section 401 (of the FD&C Act) that is not identical to such standard of identity or that is not identical to the requirement of section 403(g) of the FD&C Act (21 U.S.C. 343(g)). The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the NLEA, Pub. L. 101-535, 104 Stat. 2353, 2364 (1990)).

This final rule will impose requirements that fall within the scope of section 403A(a) of the FD&C Act.

V. Environmental Impact

We have determined under 21 CFR 25.32(a) 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.

VI. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Reference

The following reference is on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at http://www.regulations.gov. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. A.C. Nielsen Scantrack data, (2001-2010). The Nielsen Company, 770 Broadway, New York, NY 10003-9595 (http://www.acnielsen.com/).

List of Subjects in 21 CFR Part 150

Food grades and standards, Fruits.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 150 is amended as follows:

PART 150--FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

1. The authority citation for 21 CFR part 150 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§ 150.141 [Removed]

2. Remove § 150.141.

§ 150.161 [Removed]

3. Remove § 150.161.

Dated: November 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-29631 Filed: 11/19/2015 8:45 am; Publication Date: 11/20/2015]