

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. FDA-2009-P-0147]

Flavored Milk; Petition to Amend the Standard of Identity for Milk and 17 Additional Dairy Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments, data, and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) have filed a petition requesting that the Agency amend the standard of identity for milk and 17 other dairy products to provide for the use of any safe and suitable sweetener as an optional ingredient. FDA is issuing this notice to request comments, data, and information about the issues presented in the petition.

DATES: Submit either written or electronic comments by May 21, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2009-P-0147 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and

docket number for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Daniel Y. Reese, 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. IDFA and NMPF Petition

The IDFA and NMPF jointly submitted a citizen petition (Ref. 1) on March 16, 2009, requesting that FDA amend the standard of identity in part 131 (21 CFR part 131) for milk (§ 131.110). Specifically, the petition requests that FDA amend § 131.110(c)(2) to allow the use of “any safe and suitable” sweetener in optional characterizing flavoring ingredients used in milk.¹ The petition also requests that FDA similarly amend the standards of identity for 17 other milk and cream products. Those standards (hereinafter referred to as the “additional dairy standards”) are as follows: Acidified milk (§ 131.111), cultured milk (§ 131.112), sweetened condensed milk (§ 131.120), nonfat dry milk (§ 131.125), nonfat dry milk fortified with vitamins A and D (§ 131.127), evaporated milk (§ 131.130), dry cream (§ 131.149), heavy cream (§ 131.150), light cream (§ 131.155), light whipping cream (§ 131.157), sour cream (§ 131.160), acidified sour cream (§ 131.162), eggnog (§ 131.170), half-and-half (§ 131.180), yogurt (§ 131.200), lowfat yogurt (§ 131.203), and nonfat yogurt (§ 131.206). The petition asks that the standards of identity for these products

be amended to provide for the use of any safe and suitable sweetener in the optional ingredients.²

IDFA and NMPF request their proposed amendments to the milk standard of identity to allow optional characterizing flavoring ingredients used in milk (e.g., chocolate flavoring added to milk) to be sweetened with any safe and suitable sweetener—including non-nutritive sweeteners such as aspartame. IDFA and NMPF state that the proposed amendments would promote more healthful eating practices and reduce childhood obesity by providing for lower-calorie flavored milk products. They state that lower-calorie flavored milk would particularly benefit school children who, according to IDFA and NMPF, are more inclined to drink flavored milk than unflavored milk at school. As further support for the petition, IDFA and NMPF state that the proposed amendments would assist in meeting several initiatives aimed at improving the nutrition and health profile of food served in the nation’s schools. Those initiatives include state-level programs designed to limit the quantity of sugar served to children during the school day. Finally, IDFA and NMPF argue that the proposed amendments to the milk standard of identity would promote honesty and fair dealing in the marketplace and are therefore appropriate under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

The petition acknowledges that the use of non-nutritive sweeteners in optional characterizing flavoring

² The National Yogurt Association (NYA) submitted a citizen petition on February 18, 2000 (Docket No. FDA-2000-P-0126) that requested that FDA make similar changes to the standards of identity for yogurt and cultured milk. Among other requested changes, the NYA petition asked that FDA amend the standards of identity for yogurt and cultured milk to permit the use of all safe and suitable sweeteners, while also revoking the standards of identity for lowfat and nonfat yogurt. In 2009, FDA proposed to grant the petition in part, and to deny it in part. See “Milk and Cream Products and Yogurt Products; Proposal to Revoke the Standards for Lowfat and Nonfat Yogurt and to Amend the Standard for Yogurt” (74 FR 2443, January 15, 2009). Thus, FDA has already requested comments on issues that are similar to the issues IDFA and NMPF raise with respect to yogurt, lowfat yogurt, nonfat yogurt, and cultured milk, and is addressing those issues through the rulemaking initiated in response to NYA’s petition. Therefore, FDA is not currently requesting comments on IDFA and NMPF’s suggested amendments to the yogurt, lowfat yogurt, nonfat yogurt, and cultured milk standards.

¹ Section 131.110(c)(2) currently allows the use of “nutritive sweetener” in optional characterizing flavoring ingredients used in milk.

ingredients in milk is allowed under the existing regulatory scheme, with certain additional requirements. The regulatory framework governing the naming of standardized foods that do not fully comply with the relevant standards of identity changed with the passage of the Nutrition Labeling and Education Act of 1990 and FDA's rulemaking establishing the Agency's requirements for foods named by use of a nutrient content claim and a standardized term (§ 130.10 (21 CFR 130.10)). Section 130.10(d) 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. Therefore, while the milk standard of identity in § 131.110 only provides for the use of "nutritive sweetener" in an optional characterizing flavor, milk may contain a characterizing flavor that is sweetened with a non-nutritive sweetener if the food's label bears a nutrient content claim (e.g., "reduced calorie") and the non-nutritive sweetener is used to add sweetness to the product so that it is not inferior in its sweetness property compared to its standardized counterpart. However, IDFA and NMPF argue that nutrient content claims such as "reduced calorie" are not attractive to children, and maintain that consumers can more easily identify the overall nutritional value of milk products that are flavored with non-nutritive sweeteners if the labels do not include such claims. Further, the petitioners assert that consumers do not recognize milk—including flavored milk—as necessarily containing sugar. Accordingly, the petitioners state that milk flavored with non-nutritive sweeteners should be labeled as milk without further claims so that consumers can "more easily identify its overall nutritional value."

As to the additional dairy standards, IDFA and NMPF state that administrative efficiency counsels in favor of similar changes. As long as FDA is dedicating resources to amending the standard of identity for milk, they argue, the Agency should also amend the standards for these products at the same time. They state that it is most efficient to consider all of the proposals together. According to the petition, the requested changes to the additional dairy standards present the same issues as the milk standard, and it is therefore

appropriate to consider all of the requested changes together.

II. Request for Comments

FDA requests that interested persons submit comments, data, and information concerning the need for, and the appropriateness of, amending the standard of identity for milk and the additional dairy standards. FDA specifically requests comment and supporting data, as appropriate, on the following matters:

1. The petition states that amending the standard of identity for milk (§ 131.100) to allow the use of "any safe and suitable" sweetener in optional characterizing flavoring ingredients would promote honesty and fair dealing in the interest of consumers by creating consistency in the naming of flavored milk products because flavored milk could contain a non-nutritive sweetener without bearing a nutrient content claim (e.g., "reduced sugar") as part of its name. Would the proposed amendments promote honesty and fair dealing in the interest of consumers?

2. If the standard of identity for milk is amended as requested by petitioners, milk manufacturers could use non-nutritive sweeteners in flavored milk without a nutrient content claim in its labeling. Will the inclusion of the non-nutritive sweeteners in the ingredient statement provide consumers with sufficient information to ensure that consumers are not misled regarding the characteristics of the milk they are purchasing?

3. The petition states that flavored milk labels that bear nutrient content claims such as "reduced calorie" are unattractive to children. What, if any, data are available on children's purchase habits with regard to flavored milks labeled as "reduced calorie flavored milk," "no sugar added," "less sugar," etc?

4. The petition states that if FDA dedicates resources to amending the standard of identity for milk, for purposes of administrative efficiency the Agency should also amend the Additional Dairy Standards because the issues presented are the same with respect to the use of non-nutritive sweeteners. Would amending the Additional Dairy Standards as requested promote honesty and fair dealing in the interest of consumers? If the labels of these products do not bear nutrient content claims, would the inclusion of non-nutritive sweeteners in the ingredient statements provide consumers with sufficient information to distinguish between the two types of products (i.e., sweetened with nutritive

versus non-nutritive sweeteners) so that consumers are not misled?³

5. The petition notes that ice cream is permitted to contain either a nutritive or non-nutritive sweetener without the label bearing a nutrient content claim or otherwise distinguishing the two types of products from one another. Are the considerations underlying FDA amendments to the standard of identity for ice cream⁴ applicable to the requested amendments to the standard of identity for milk or the Additional Dairy Standards?

6. If the standard of identity for milk and the Additional Dairy Standards are amended in the manner requested by the petition, what will be the effect on search costs⁵ for consumers who would like to determine whether a product contains a nutritive or non-nutritive sweetener?

After reviewing the comments received, FDA will further evaluate the need for, and appropriateness of, the amendments requested by IDFA and NMPF and will decide what further actions are appropriate. For a copy of the petition filed by IDFA and NMPF please go to: <http://www.regulations.gov> and insert "Docket No. FDA-2009-P-0147" into the "Search" box.

(Authority: 21 U.S.C. 321 *et seq.*)

III. References

FDA has placed the following references on display. To view the references, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box. The references may also be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

1. International Dairy Foods Association and the National Milk Producers Federation, Citizen Petition, March 16, 2009.

³ Although FDA requests comments relevant to the IDFA and NMPF petition, FDA does not seek comments regarding the requested amendments to the standards of identity for yogurt, lowfat yogurt, nonfat yogurt, and cultured milk. FDA has already sought and collected comments regarding similar amendments to those standards in a proposed rulemaking. See 74 FR 2443.

⁴ FDA amended the standard of identity for ice cream to allow for "any safe and suitable sweetener" to be used in ice cream. See "Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat's Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat's Milk Ice Cream" (59 FR 47072, September 14, 1994) (Ref 2). Before FDA's amendment, the standard provided only for "nutritive carbohydrate sweeteners."

⁵ Search costs include the time and energy it would take an average consumer to read a label and determine whether the product contained the nutritive sweetener or the artificial sweetener.

2. "Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat's Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat's Milk Ice Cream" (59 FR 47072, September 14, 1994).

Dated: February 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-03835 Filed 2-19-13; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 543

RIN 3141-AA27

Minimum Internal Control Standards

AGENCY: National Indian Gaming Commission.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission (NIGC) proposes to amend its minimum internal control standards for Class II gaming under the Indian Gaming Regulatory Act to add standards for the drop and count and surveillance of kiosks.

DATES: Submit comments on or before April 22, 2013.

ADDRESSES: You may submit comments by any one of the following methods, however, please note that comments sent by electronic mail are strongly encouraged.

■ *Email comments to:* reg.review@nigc.gov.

■ *Mail comments to:* National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005.

■ *Hand deliver comments to:* 1441 L Street NW., Suite 9100, Washington, DC 20005.

■ *Fax comments to:* National Indian Gaming Commission at 202-632-0045.

FOR FURTHER INFORMATION CONTACT: National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005. Telephone: 202-632-7009; email: reg.review@nigc.gov.

SUPPLEMENTARY INFORMATION:

I. Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions

presented are particularly helpful in developing reasoned regulatory decisions on the proposal.

II. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100-497, 25 U.S.C. 2701 *et seq.*, was signed into law on October 17, 1988. The Act establishes the National Indian Gaming Commission ("NIGC" or "Commission") and sets out a comprehensive framework for the regulation of gaming on Indian lands. On January 5, 1999, the NIGC published a final rule in the *Federal Register* called *Minimum Internal Control Standards*. 64 FR 590. The rule added a new part to the Commission's regulations establishing Minimum Internal Control Standards (MICS) to reduce the risk of loss because of customer or employee access to cash and cash equivalents within a casino. The rule contains standards and procedures that govern cash handling, documentation, game integrity, auditing, surveillance, and variances, as well as other areas.

The Commission recognized from their inception that the MICS would require periodic review and updates to keep pace with technology, and has amended them numerous times, most recently on September 21, 2012. 77 FR 58708.

III. Development of the Proposed Rule

On September 21, 2012, the Commission concluded nearly two years of consultation with the publication of comprehensive amendments, additions, and updates to Part 543, the minimum internal control standards (MICS) for Class II gaming operations. The regulations require tribes to establish controls and implement procedures at least as stringent as those described in this part to maintain the integrity of the gaming operation and minimize the risk of theft.

One of the 2012 additions was the inclusion of kiosks, devices capable of redeeming vouchers or and/or wagering credits or initiating transfers from a patron deposit account. The regulation provided general standards for kiosks, but upon further review, additional standards are needed for the drop and count and surveillance of kiosks to adequately protect against risk of loss.

Regulatory Matters

Regulatory Flexibility Act

The proposed rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian

Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of \$100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions, nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the proposed rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the proposed rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the proposed rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget as required by 44 U.S.C. 3501, *et seq.*, and assigned OMB Control Number 3141-0009. The OMB control number expires on October 31, 2015.