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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

**Subject: Docket No. 2004P-0294: Proposed Rule -- Food Labeling; Health Claims;
Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries**

McNeil Nutritionals, LLC, submits the following comments in response to the proposed rule to amend the non-cariogenic dental health claim (21 CFR §101.80) to permit sucralose as an eligible substance for the claim. McNeil Nutritionals, LLC, is the sponsor of the health claim petition upon which the proposed rule is based.

We support this action to permit eligibility of sucralose for the claim. Our comments address certain aspects of the preamble to the proposed rule specifically with respect to the applicability of the proposal to sucralose-based table sweeteners sold by McNeil under the SPLENDA® Brand name.

Applicability of the proposal to sucralose-based SPLENDA® Brand Products

The preamble to the health claim rule proposes that the retail sugar substitute products, SPLENDA® No Calorie Sweetener Granular and Packets should not be eligible for the health claim.

We object to FDA's inclusion of the McNeil retail sugar substitute products in the preamble by name. In our view, a reference to the eligibility of a sucralose-based sugar substitute should have been generic. Clearly, any sucralose-based sugar substitute product that fails to meet the criteria set forth in 21 CFR §101.80 would be ineligible for the dental health claim, not only the McNeil products. FDA's conclusions should have referred to the eligibility of those sucralose-based sugar substitute formulations containing sugars and/or other fermentable carbohydrate bulking agents, such as dextrose, maltodextrin, lactose, etc., that do not meet the criteria of 21 CFR §101.80(c)(2)(iii)(A) and (C).

If 21 CFR §101.80 is amended to include sucralose, there is nothing to prevent McNeil from reformulating the sucralose-based granular and packet products to bring them into compliance with 21 CFR §101.80(c)(2)(iii)(A) and (C) and selling them under the SPLENDA® Brand name. We recognize that the end use of sugar substitutes is integral to their usefulness in promoting better dental health. To ensure that this important fact is passed on to consumers, appropriate information statements on labeling and other materials could be used to communicate the usefulness of these products accurately. In fact, this would be analogous to information provided to consumers with diabetes who use sugar substitute products. That is, they must consider the foods they sweeten with sugar substitutes and the portion sizes they consume when assessing dietary impact.

We also note that nowhere in the petition did McNeil, the sponsor, ask or seek to have FDA specifically include SPLENDA® No Calorie Sweetener Granular (bulked with maltodextrin) and Packets (bulked with dextrose + maltodextrin) or the SPLENDA® Sugar Blend For Baking as products eligible for the claim. Indeed, the SPLENDA® Sugar Blend For Baking was not even on the market at the time the petition was submitted and, as the petitioner, McNeil never sought to amend the petition to include it in subsequent information submitted to FDA. In fact, the SPLENDA® Brand name appears nowhere in the petition.

While we acknowledge that the petition included pH data from three studies involving sucralose-based maltodextrin- and dextrose-bulked table sweeteners, these studies were

performed and submitted to support the eligibility of sucralose for the claim, not for the eligibility of the finished retail products.

We note that the existing health claim (21 CFR §101.80) provides for a number of eligible food ingredient substances, all identified by their generic names, e.g., erythritol, tagatose, etc., not for finished products containing these substances, which may or may not qualify for the claim based on 21 CFR §101.80(c)(2)(iii)(C). Clearly, the eligible ingredients are not consumed on their own. Nonetheless, the current dental health claim rule does not specify a list of finished retail products eligible for the claim in which these substances are incorporated. Rather, eligibility of a finished retail product for the claim, like SPLENDAs[®] No Calorie Sweetener Granular and Packets, would be contingent upon meeting the criteria of 21 CFR §101.80(c)(2)(iii)(A) and (B) or (C), where:

- (A) The food shall meet the requirements of 21 CFR §101.60(c)(1)(i), i.e., less than 0.5g sugars per serving, thus qualifying for a “sugar free” claim, and
- (B) The food...shall contain one or more of the noncariogenic carbohydrate sweeteners listed in paragraph (c)(2)(ii) of this section, and
- (C) When carbohydrates other than those listed in paragraph (c)(2)(ii) of this section are present in the food, the food shall not lower plaque pH below 5.7 by bacterial fermentation either during consumption or up to 30 minutes after consumption, as measured by the indwelling plaque pH test found in “Identification of Low Caries Risk Dietary Components,” dated 1983, by T. N. Imfeld, in Volume 11, Monographs in Oral Science, 1983.

The SPLENDAs[®] No Calorie Sweetener -- Granular form complies with subpart (A) in that it is “sugar free”. The granular product also would comply with subpart (B), with the addition of sucralose to the list of noncariogenic carbohydrate sweeteners. With respect to subpart (C), the SPLENDAs[®] Granular product does contain fermentable carbohydrate (maltodextrin) per 0.5 g serving. Thus, as provided by 21 CFR §101.80(c)(2)(iii)(C), a food or beverage made with the SPLENDAs[®] Granular product must not lower plaque pH below 5.7, either during consumption or up to 30 minutes thereafter, as measured by the in-dwelling electrode method. In Section IV of the preamble to the proposed rule, FDA concludes that the dental caries health claim on the SPLENDAs[®] Granular product would not be appropriate, because the “petitioner’s micro-touch electrode pH measurement do not satisfy the pH evidence requirement”.

McNeil believes that the information contained in the petition is insufficient to warrant this conclusion. The petition information on which FDA has relied involves a study in which a formulation consisting of sucralose + maltodextrin equivalent to “two teaspoons of sucrose” (sugar) was used to rinse the mouth before the pH measurement. The preamble mistakenly notes that this quantity represents “one serving” of the “Splenda Granular” product. This is incorrect. Rather, this quantity is double the “Splenda Granular” reference amount customarily consumed (RACC) [See 21 CFR §101.12(b) Table 2]. One RACC of a “sugar substitute”, e.g., Splenda Granular, is the quantity equal in sweetness to “one teaspoon” of sugar, not two teaspoons. Thus, the pH effect of “one serving” of the Splenda Granular in a drink, e.g. tea or coffee, when assessed by the preferred in-dwelling electrode method, remains an open question. Even though the information contained in the petition, which was based on two teaspoons of a Splenda Granular-equivalent formulation, the pH was not lowered below 5.7, FDA disqualified the data because it did not involve the use of the preferred pH method. However, if a single serving of a sucralose + maltodextrin formulation (e.g., Splenda Granular) is shown not to lower plaque pH below 5.7, when measured by the preferred method, the product should be eligible for

the health claim. As noted above, the product also could be made eligible by reformulating it with a non-fermentable carbohydrate bulking agent, e.g., erythritol.

We also note that in its “Analysis of Impacts” (Section VII, p. 25501), FDA again refers to “Splenda Granular” by name when stating that the eligibility of the product for the claim would make consumers “worse off”. The agency’s reasoning is that “the intended use of Splenda Granular is in the preparation of food likely to lower plaque pH below 5.7, when measured by the indwelling electrode method.” The preamble goes on to state that the product is “also designed to be used in the cooking and baking of many foods containing starch. Since foods containing starch are associated with...increased risk of dental caries, consumers would not benefit from seeing the health claim on products such as Splenda Granular”.

The intended use of the Splenda Granular product is as a sugar substitute, not in the preparation of food likely to lower plaque pH below 5.7. The fact it can be used in cooking and baking owes to the heat stability of sucralose. It is true that, when used to sweeten a food (whether cooked, baked, or otherwise) that itself contains fermentable carbohydrate, the food (as consumed) may not offer any dental health benefit over a comparable sugar-sweetened version. But, this would be true even if pure sucralose were used to sweeten a starch-laden food.

We also challenge the agency’s assumptions on the end use of the Splenda Granular product. Our consumer research shows that the largest percentage (58%) of use for this product is in beverages, e.g., coffee, tea, powdered soft drinks, where it does have the potential to provide a dental health benefit. Accordingly, at issue is the end use of a sucralose + maltodextrin sugar substitute, not the product itself. In our view, assuming that a sucralose + maltodextrin sugar substitute product meets the requirements of §101.80(c)(2)(iii)(C), it should be allowed to bear the health claim. Label information about the end use of the product could address concerns about the lack of dental health benefit when the product is used to sweeten foods and beverages with fermentable carbohydrate.

Elsewhere in the preamble to the proposed rule, FDA notes that Splenda Packets contain in excess of 0.5 g of dextrose per RACC and per labeled serving and, thus, do not meet the “sugar free” requirement of 21 CFR §101.80. As a consequence FDA concludes that the product is not eligible for the dental caries health claim. The preamble goes on to note that “the petition did not request amendment to the ‘sugar free’ requirement, nor has the agency considered amending this paragraph”. Thus, the preamble notes that the agency did not consider information on the plaque pH effect of a sucralose + dextrose blend that is contained in published information submitted with the petition.

As noted above for the Splenda Granular product, we believe the preamble should not refer to specific product brand names. Like the Splenda Granular product, it would be simple for McNeil to reformulate Splenda Packets to lower the level of dextrose in each packet from its present level of less than one gram to less than 0.5 gram in order to meet the “sugar free” claim. Or, a non-fermentable bulking agent could be substituted. In each case, the product could be sold under the same brand name and, provided it met the conditions of a sucralose-amended 21 CFR §101.80, it should be eligible for the dental health claim.

Furthermore, for any sucralose + sugar blend, the test of whether the dental health claim would apply should be based on the performance standard established by FDA in part 21 CFR §101.80(c)(2)(iii)(C), regardless of whether the product qualifies for a “sugar free” claim. If plaque pH is not lowered below 5.7 by the indwelling pH method preferred by FDA, does it matter how much sugar the product contains on a per serving basis? Isn’t the pH performance standard more important to the potential for improved dental health than a few tenths of a milligram of sugar in excess of the 0.5 g limit for a “sugar free”

claim? Accordingly, we would argue that the “sugar free” standard is a superfluous requirement when the product meets the performance standard set by FDA. Thus, if a sucralose sugar substitute formulation with >0.5 g sugar per serving is shown to meet the pH performance standard set by FDA, it should be eligible for the claim.

McNeil is unaware of any evidence showing the fermentability of sucralose

In the preamble “Summary”, FDA states that sucralose is “minimally fermented”. McNeil is unaware of any scientific evidence that would suggest that sucralose is fermented at all by oral bacteria or by bacteria elsewhere in the body. Elsewhere in the “Summary”, FDA again notes that sucralose is “not fermented by oral bacteria to an extent sufficient to lower dental plaque pH...”. Extensive scientific data contained in the sucralose food additive petitions and data in the sucralose dental health claim petition demonstrate that sucralose is not fermented at all.

We commend FDA’s action on the petition to permit the eligibility of sucralose for a dental health claim and we appreciate the opportunity to comment.

Sincerely,

Richard Reo
Director, Regulatory Affairs