



30th March 2012

The COAG Legislative and Governance Forum on Food Regulation
Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
Australia

Dear Sir or Madam,

Re: Submission on Draft Proposal P293 – Nutrition, Health and Related Claims

Johnson & Johnson Pacific Pty Ltd (JJPL) welcomes the opportunity to comment on the draft Food Standard 1.2.7. JJPL markets one nutritional product (Splenda[®] – sucralose) which may be affected by the above proposal therefore our comments are limited only to issues which may relate to the claims that are used for this product.

Sucralose is a low calorie, non-nutritive sweetener which is approved for use in Australia, New Zealand, US, Europe and many other countries.

Sucralose and sucralose sweetened foods and beverages may be useful tools in the dietary management of individuals with, or at risk of diabetes, a disease that has increased significantly with the recent increases in the incidence of obesity.¹

In this context, JJPL currently makes claims on Splenda[®] products such as “suitable for use by diabetics” and “may be used by diabetics”. This claim may be interpreted as being a health claim, however the draft standard, as currently written, makes no allowance for these claims to be used for Splenda[®] granules or sweetening tablets (one tablet / sachet is equivalent sweetness to one teaspoon of sugar). Many scientific and clinical studies have been conducted using Splenda[®], which confirm its suitability for use in diabetic individuals. JJPL is willing to provide this information to FSANZ on request.

JJPL believes that the statements “Suitable for use by diabetics” and “May be used by diabetics” are in the interests of consumers and an important public health message, informing them that there is an alternative to sugar which may be suitable for them to use.

We therefore request that the statements above be included in the draft Food Standard 1.2.7. This will allow for clear guidance on how the claims may be used and will specify the types of foods and nutrient profile of food products that may use the claims. Attached is the tabled template relating to this proposal.

Yours sincerely,



Julie Viatos
Consultant, Regulatory Affairs, OTC

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References:

1. Grotz V.L. et al. Lack of effect of sucralose on glucose homeostasis in subjects with type 2 diabetes. J. Am Diet Assoc. 2003; 103: 1607-1612

Attachment D – Template for submissions – Proposal P293 – Nutrition, Health & Related Claims

To assist us in compiling submissions, please complete the tables below.

Table 1: Revised draft Standard 1.2.7

Submitter name: Julie Viatos, Consultant – Regulatory Affairs - OTC Johnson & Johnson Pacific Pty Ltd	
<p>1. Does the revised drafting accurately capture the regulatory intent as provided in Attachment B? Please consider the clarity of drafting, any enforceability issues and the level of ‘user-friendliness’.</p> <p>If not, please provide specific details in the table below. Ensure that the relevant clause number, schedule number or consequential variation item number that you are commenting on is clearly identified in the left column. Lines may be added if necessary.</p>	
Clause number	Comment
Clause 2 - Interpretation	<p>Splenda®(sucralose) in granule and tablet forms for use as a non-nutritive, low calorie sweetener currently makes the label / claims statement “Suitable for use by diabetics” and “May be used by diabetics”.</p> <p>Although this claim may be interpreted as a statement of fact – i.e. whether diabetic individuals may use the food product, or describing the use or property of the food, the statement also has the potential to be interpreted as a health related claim or a therapeutic claim.</p> <p>In providing this submission to FSANZ, JJPL requests that this claim should be allowed in the standard, for use by specific low calorie, non-nutritive sweetening products, allowed elsewhere in the code as sweeteners.</p> <p>Foods that contain the sweetener could also be specified according to nutrient profiles.</p>

<p>Clause 7 – Claims must not be of a therapeutic nature</p>	<p>JJPL is concerned that the claims of “suitable for use by diabetics” and “may be used by diabetics” may possibly be interpreted as therapeutic claims.</p> <p>The Clause 7 of the draft standard may therefore restrict the use of, or disallow the claims currently being used.</p> <p>This is of concern to JJPL and may also be a concern for consumers, who will be denied information on the suitability for use of the product.</p> <p>Splenda[®] meets the strictest criteria for reduced energy and reduced sugar foods as shown in the Nutrient Profiling.</p> <p>The proposed claims relate only to suitability for use by diabetic individuals and do not imply that their use will treat, improve, or delay diabetes.</p> <p>The Therapeutic Goods Act 1989 defines therapeutic use as:</p> <p><i>therapeutic use means use in or in connection with:</i></p> <ul style="list-style-type: none"> <i>(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or</i> <i>(b) influencing, inhibiting or modifying a physiological process in persons; or</i> <i>(c) testing the susceptibility of persons to a disease or ailment; or</i> <i>(d) influencing, controlling or preventing conception in persons; or</i> <i>(e) testing for pregnancy in persons; or</i> <i>(f) the replacement or modification of parts of the anatomy in persons.</i> <p>The claims currently made for Splenda[®] (i.e. suitable for use in diabetics, may be used by diabetics) arguably do not clearly meet this definition, however it is in the interests of regulators, sponsors as well as consumers, that there be some clear and consistent guidance on the use of these claims for the specified products.</p>
<p>Clause 12 (1)(a): Nutrition content claims about properties of a food not in Schedule 1 may only state that the food does or does not contain the property of food.</p>	<p>Since the claims “Suitable for use by diabetics” or “may be used by diabetics” does not appear in Schedule 1, JJPL is uncertain about whether the desired claims are able to be used.</p>

Schedule	Comments
Schedule 1: Conditions for Nutrient Content Claims	<p>Schedule 1 contains no entries that relate directly to products such as Splenda®. The product is non-nutritive so it does not fit within the nutrient content claims framework. Although a claim of sugar-free could be made, this claim is not sufficiently detailed, descriptive or helpful to diabetic consumers, who would like to know whether or not the product may be used by them.</p> <p>This leaves a degree of uncertainty for both sponsors and consumers.</p>
Schedule 2: Conditions for permitted health claims.	<p>The statement “suitable for diabetics” or “may be used by diabetics” does not appear in Schedule 2. If the claims are interpreted as being therapeutic in nature or health claims, these default to high-level health claims which are prohibited.</p> <p>This situation is not in the interests of public health and is inconsistent and confusing for regulators, sponsors and consumers alike. It will lead to the situation where certain foods make other health and therapeutic claims (e.g. relating to osteoporosis, blood coagulation, immune system function, energy metabolism, blood formation, reduces blood cholesterol etc) – but will not be provided with important information such as whether this particular food is suitable for their medical condition.</p> <p>We request that FSANZ consider this situation and make some allowances for products such as Splenda®, and allow for claims to be made on their suitability for use by people with diabetes.</p>

Consequential variations	Comments
<p>Either Schedule 1: Conditions for Nutrient Content Claims OR Schedule 2: Conditions for Permitted Health Claims</p>	<p>JJPL proposes that FSANZ make some allowance for the claims “suitable for diabetics” and “may be used by diabetics”.</p> <p>Schedule 1 defines conditions for nutrient content claims. As mentioned above, Splenda[®] has no nutritional value per se, other than being used for its sweetening properties. One Splenda[®] tablet used for sweetening purposes contains 0.8kJ (less than 1 g carbohydrate). Splenda granules (used as a sweetener for cooking) contain 8kJ (less than 1 g carbohydrate) per metric teaspoon. We request that FSANZ consider whether Splenda[®] (sucralose) has a place within Schedule 1 or whether Schedule 1 should be amended to allow for a non-nutritive sweetening product. This could be linked to a “sugar free” category.</p> <p>Schedule 2 lists conditions that must be met for permitted health claims. We request that FSANZ consider whether schedule 2 should be amended to allow for “suitable for use by diabetics” or “may be used by diabetics” for sweeteners such as sucralose, when these contain less than 1g of carbohydrate per specified serving size.</p> <p>Amending the schedules to allow for the claims currently being made for Splenda[®] products would provide some certainty and guidance for sponsors, and be beneficial for consumers who rely on this type of information in order to make decisions about their food and health.</p> <p>JJPL believes that the claims of “suitable for use by diabetics” or “may be used by diabetics” are accurate, do not imply treatment or alleviation of a medical condition, and should be allowed for within the Food Standards framework in order to eliminate any confusion and uncertainty.</p>