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Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Bureau of Nutritional Sciences
Food Directorate
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April 25, 2013
File #: FB-10-0003

Scott J. Smith
Vice President
Taiyo International, Inc.
5960 Golden Hills Drive
Minneapolis MN 55416
USA

Dear Mr. Smith,

Subject: The use of Sunfiber® as a source of dietary fibre source in Canada

This is in response to your application received August 12, 2010, requesting approval for labelling Sunfiber®, a partially hydrolyzed guar gum (PHGG), as a dietary fibre source.

We have completed the review of the information included in the original submission of August 2010 and the additional information received in March, January and August 2012 and April 2013 and have the following comments.

Under the revised policy released in February 2012 (Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products), your product is considered as a novel fibre source and its safety and a physiological effect should be demonstrated to allow its use as a dietary fibre source.

The evidence available showed that the addition of Sunfiber® to foods results in more than 20% reduction in postprandial blood glucose levels, considered as the minimum reduction acceptable as per Health Canada's Guideline 1997 (*Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them*). Therefore, Health Canada has no objection to the use of Sunfiber®, as a dietary fibre source in unstandardized foods, except infant formula. The use of partially hydrolyzed guar gum in infant formula would be permitted provided that a safety assessment was conducted and that a Letter of No Further Questions was issued by the Food Directorate. Its addition to standardized foods as per the Food and Drug Regulations as a fibre ingredient is not permitted, unless a provision for the addition exists in the Regulations.

Please note that "chewable tablets" may fall at the food-Natural Health Product (food-NHP) interface depending on the product representation, public perception and history of use, and product composition. Please contact us if you would like to make a formal classification request.

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The label claims permitted for foods containing Sunfiber® are limited to the declaration of dietary fibre content and source claims as per the Food and Drug Regulations (Table following B.01.513, item 41-44).

As per the Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products, an energy value of 2kcal (8kj)/g should be used for the fibre fraction of this product.

The common name to be used for Sunfiber® on food labels is "Partially Hydrolyzed Guar Gum".

We would like to remind Taiyo International, Inc. to take the necessary precautions to ensure that Sunfiber® is not contaminated with pentachlorophenol or dioxins as a result of the use of guar gum as an initial product. It is the continuing responsibility of the manufacturer to ensure that marketed products are in compliance with all applicable statutory and regulatory requirements. The sale of a food which poses a health hazard to consumers would contravene the provisions of the Food and Drugs Act.

Yours sincerely,



Lynne Underhill, M.Sc.
Chief, Nutrition Premarket Assessment Division

cc: Luc Rivard, Director,
Consumer Protection Division,
Canadian Food Inspection Agency

Gustavo A. Gonzalo, Sales Manager,
Taiyo International, Inc.