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JUL 31 2003

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Ms. Cassandra A. Soltis, Esq.  
Hyman, Phelps & McNamara, P.C.  
700 Thirteenth Street, N.W.  
Suite 1200  
Washington, D.C. 20005-5929

Dear Ms. Soltis:

This is in response to your letters to the Food and Drug Administration (FDA) dated July 17, 2003 on behalf of Purac Biochem b.v., Gorinchem, The Netherlands. Your letters were submitted pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Purac Biochem b.v. is making the following representation, among others, for its product **Lacty**:

“Lactitol is a low glycemic sweetener.”

21 U.S.C. 321(ff) defines the term “dietary supplement.” As defined by the Act, dietary supplements do not include products represented for use as conventional foods. 21 U.S.C. 321(ff)(2)(B). The statement above evidences that the intended use of **Lacty** is, in part, as a sweetener. Sweeteners are conventional foods. Given this representation for the product’s intended use, **Lacty** is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, **Lacty** is a conventional food and it must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, **Lacty** must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 403(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market **Lacty** as a sweetener and you have any questions about the status of its ingredients, you should direct them to FDA’s Office of Food Additive Safety (HFS-200), 200 C St., SW, Washington, DC 20204.

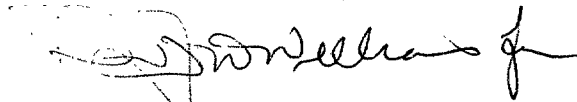
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Page 2 - Ms. Cassandra A. Soltis

Please contact us if we may be of further assistance.

Sincerely, yours,

A handwritten signature in black ink, appearing to read "Susan J. Walker". The signature is written in a cursive style with a long, sweeping tail on the final letter.

Susan J. Walker, M.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

Copy:

Mr. P. H. J. Mesters  
Purac Biochem b.v.  
Arkelsedijk 46  
P.O. Box 21  
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The Netherlands

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MARY KATE WHALEN  
OF COUNSEL

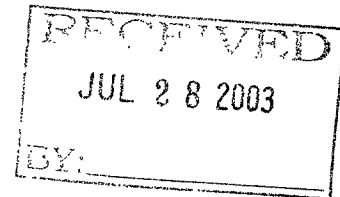
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\*NOT ADMITTED IN DC

DIRECT DIAL (202) 737-4295

July 17, 2003

Office of Nutritional Products, Labeling,  
and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740



NOTIFICATION OF STATEMENTS  
OF NUTRITIONAL SUPPORT

On behalf of Purac Biochem b.v., Arkelsedijk 46, P. O. Box 21, 4200 AA Gorinchem, The Netherlands, the undersigned files this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6). The certification required by 21 C.F.R. § 101.93(a)(3) is attached.

Brand Name: Lacty

Dietary Ingredients: Lactitol

Statements of Nutritional Support:

1. Lactitol is a low glycemic sweetener.
2. Lactitol has a low glycemic index.

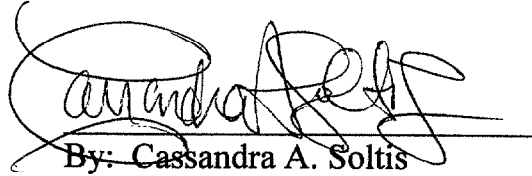
85269

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SUITE 400  
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3. Lactitol may be useful in a low glycemic diet.

Hyman, Phelps & McNamara, P.C.



By: Cassandra A. Soltis

Attachment – Certification

21 C.F.R. § 101.93(a)(3) Certification

I certify that the information contained in the preceding section 403(r)(6) notice for Lacty is complete and accurate and that Purac Biochem b.v. has substantiation that the statements are truthful and not misleading.

A handwritten signature in black ink, appearing to read 'P.H.J. Mesters', written over a horizontal line.

P.H.J. Mesters  
B.U. Manager Lactitol

July 11, 2003