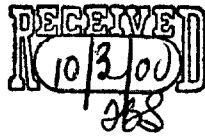




McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington, PA 19034-2299 (215) 273-7000

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Felicia B. Satchell
Division of Standards and
Labeling Regulations, HFS-820
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

RE: New Dietary Ingredient Notification for *Lactobacillus Reuteri*

Dear Ms. Satchell:

This is a follow up to your September 18, 2000 letter and our subsequent September 28, 2000 meeting concerning McNeil Consumer Healthcare's new dietary ingredient notification dated June 30, 2000. Your letter had expressed FDA concerns about the adequacy of the evidence supporting use of this product among infants and children under two years of age. This confirms that the subject of the notification, a *Lactobacillus reuteri* dietary supplement product, is not intended for use by infants and children under two years of age, and the notification submitted was not intended to support such use.

As McNeil also confirmed at the meeting, subsequent label and appropriate labeling materials will be revised at the next printing to clarify that the product is not intended for use by children under two years of age. Indeed, the product form - a chewable tablet - is not appropriate for this population. In the future, should McNeil decide to expand the use of the *Lactobacillus reuteri* dietary supplement to infants and children under two, we will do so by way of a supplementary notification to the existing file.

McNeil requests that this letter be made a part of the new dietary ingredient notification materials and placed on public display at Dockets Management Brand, Docket No. 95S-0316.

Sincerely
MCNEIL CONSUMER HEALTHCARE

John C. Young
Director, Regulatory Affairs - Nutritionals

95S-0316

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