



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, Maryland

g. 4288d

WARNING LETTER

SEP -9 2003

Mr. Aldo Uva
President
Parmalat USA
520 Main Avenue
Wallington, New Jersey 07057

Dear Mr. Uva

The Food and Drug Administration (FDA) has reviewed the labels for your one pint containers of NATURAL BY NATURE brand "Pasteurized Organic Half-and-Half" and "Pasteurized Organic Heavy Cream." [REDACTED] The labels were collected by an FDA Investigator during an inspection of [REDACTED] conducted on June 27, 2003.

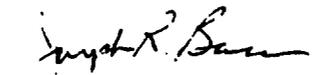
Our review reveals that these products are misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). Under Section 403(a)(1) of the Act, a product is misbranded if its labeling is false in any particular. The labels of these products contain the statement "No Hormones," which is false. This statement is false because naturally occurring hormones are present in all milk products. Due to the presence of naturally occurring hormones, milk cannot be produced in a way that renders it free of hormones. Therefore, milk products cannot be labeled in a manner that falsely indicates that hormones are not present in the product.

The above violation is not meant to be an all-inclusive list of deficiencies on your labels. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct this violation and to prevent its future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please respond in writing, within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you have taken to correct the noted violation. Copies of the revised labels for the referenced products should be submitted with your response. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed

Your response should be directed to Ray H. Abrahams, Director of Compliance, U.S. Food and Drug Administration, Waterview Corp. Center, 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054. If you have any questions regarding any issue in this letter, please contact Rich Manney, Compliance Officer, at 973-526-6008.

Sincerely yours,



Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:


President


President