

Nestlé USA

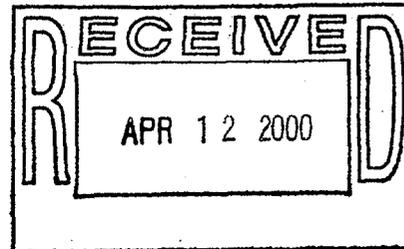
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QUALITY MANAGEMENT

March 29, 2000

Dr. Lynn A. Larsen
Office of Nutritional Products,
Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204



Re: Nestlé LC¹ with *Lactobacillus* All-Natural Probiotic Supplement

Dear Dr. Larsen:

Pursuant to the requirements in 21 C.F.R. § 101.93(a)(2), please be advised that Nestlé USA, Inc. has begun the commercialization of LC¹, a dietary supplement of *Lactobacillus* cultures. The product bears on its label the following statements as authorized by Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act:

- “all-natural probiotic supplement;”
- “daily support for your body’s immune system;”
- “with daily use, Nestlé LC¹ supports a healthy immune system;”
- “LC¹ will help restore the natural balance of healthy bacteria in your digestive tract, to aid your body’s own natural defenses;” and
- “LC¹, a revolutionary, all-natural probiotic supplement, has been proven to help support your body’s own natural immunity.”

The information in this submission is complete and accurate. Nestlé USA has substantiation on file documenting that the statements made are truthful and not misleading.

Sincerely,

Kenneth Mercurio
Director, Regulatory and Nutrition

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