



DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

MAY 26 1998

Date
From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456
Subject 75-day Premarket Notification for New Dietary Ingredient
To Dockets Management Branch, HFA-305

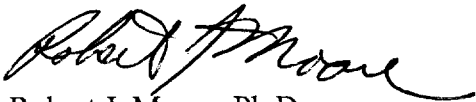
New Dietary Ingredient: *Lactobacillus casei*

Firm: LaVida Corporation

Date Received by FDA: May 15, 1998

90-day Date: August 12, 1998

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after August 12, 1998.


Robert J. Moore, Ph.D.

95S-0316

RPT 31



MAY 26 1998

Mr. Steven A. Evans
Marketing Manager
LaVida Corporation
42927 Christina Drive
Sterling Heights, Michigan 48313

Dear Mr. Evans:

This is to notify you that your submission pursuant to section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) dated May 11, 1998, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., *Lactobacillus casei*) was received by the Food and Drug Administration (FDA) on May 15, 1998. Your submission will be kept confidential for 90 days from the date of receipt, and after August 12, 1998, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

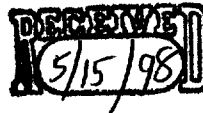
Please contact us if you have questions concerning this matter.

Sincerely,

A handwritten signature in cursive script that reads "Robert J. Moore".

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals

5/11/30



May 11, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

To Whom it May Concern,

Please find enclosed two (2) copies of our Pre-Market Notification for a New Dietary Ingredient in accordance with the Code of Federal Regulations, 21 CFR 190.6.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "S. A. Evans".

Steven A. Evans, Marketing Manager
LaVida Corporation
42927 Christina Dr.
Sterling Heights, MI 48313
Telephone: 810-997-3383
Fax: 810-997-3496
E-mail: SAE8086@Worldnet.att.net

**Pre-Market Notification
for a
New Dietary Ingredient**

Date: May 11, 1998

To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. St. SW
Washington, DC 20204

From: Mr. Steven A. Evans
LaVida Corporation
42927 Chistina Dr.
Sterling Heights, MI 48313

To Whom It May Concern,

Pursuant to the Code of Federal Regulations, 21CFR190.6, LaVida Corporation (currently operating at the address above) is issuing this premarket notification of its intent to manufacture and market a product (herein described *Lactobacillus casei* (clearans strain)) as a new dietary ingredient. We take this action with the understanding that LaVida Corporation will not market this product for a period of at least 75 days succeeding this notification and acceptance by the agency.

Company and Proposed Location of Manufacturing:

LaVida Corporation
42927 Chistina Dr.
Sterling Heights, MI 48313
Contact Person: Mr. Steven A. Evans
Telephone Number: 810-997-3383

Product Name:

Lactobacillus casei

Product Description:

Taxonomy

According to Bergey's Manual of Determinative Bacteriology, Eighth Edition, the genus **LACTOBACILLACEAE** or *Lactobacillus* family exhibit the following characteristics: straight or curved rods usually occurring singly or in chains, generally non-motile though some rare strains can be motile, gram-positive, anaerobic or facultative, has complex organic nutritional requirements, highly saccharoclastic, at least half of end product carbon from carbohydrate metabolism is lactate, lactate is not attacked anaerobically, catalase negative (no porphyrin in apoprotein), benzidine reaction negative, pathogenicity is unusual and can be found in fermenting animal and plant products where carbohydrates are available; also, found in the mouth, vagina and intestinal tracts of various warm-blooded animals, including man. *Lactobacillus casei* is listed among the many species of this family of bacteria, which also includes *L. bulgaricus*, *L. acidophilus* and *L. fermentum*. These bacteria have been identified as

having a beneficial role in the intestines of warm-blooded animals for breaking down food into constituent components that aid in the absorption of essential nutrients.

Quantity of Product per Unit

Each unit of the dietary supplement will contain approximately 1.5 billion live cells in the packaged form of either a tablet, gelatin capsule or freeze-dried powder.

Recommended Use

One to two units per day to replenish or maintain intestinal microflora balance.

Product Safety, Scientific Studies and Current Use:

Lactobacillus casei has been used as food additive for many years. It has been documented for use as a fermenting agent in yogurt, and as a preservative in dehydrated/smoked sausages. Presented below are citations (with references, abstracts and articles attached) which concern safety, scientific and commercial aspects specific to the product.

Safety of Lactic Acid Bacteria (LAB)

A reprint of a scientific paper named Safety of Probiotic Bacteria, Donohue DC, Salminen S, Asia Pacific Journal of Clinical Nutrition (1996), Vol. 5: pp. 25-28.

Scientific Studies

Abstracts obtained from scientific journals:

Milk fermented with yogurt cultures and *Lactobacillus casei* compared with yogurt and gelled milk: influence on intestinal microflora in health infants, Guerin-Danan C, et al, American Journal of Clinical Nutrition (1998), Jan.;67 (1): pp. 111-117.

Biotherapeutic role of fermented milk, Gonzalez SN, et al, Biotherapy (1994); 8 (2): pp. 129-134.

Suppressing effect of *Lactobacillus casei* administration on the urinary mutagenicity arising from ingestion of fried ground beef in the human, Hayatsu H, Hayatsu T, Cancer Letters (1993) Sep. 30; 73(2-3): pp. 173-179.

Prophylactic effect of a *Lactobacillus casei* preparation on the recurrence of superficial bladder cancer. BLP Study Group., Aso Y, Adazan H, Urology International (1992); 49(3): pp. 125-129.

Commercial Articles

Selection of several companies commercially providing products containing *Lactobacillus casei* as a dietary supplement:

American Council on Collaborative Medicine, Dallas, TX

Valley Research, Inc., South Bend, IN

Nutraceutix, Redmond, WA

Date: May 11, 1998

Signed: 
Steven A. Evans

Title: Marketing Manager, LaVida Corporation