DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date . JAN 24 2000

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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:	D-Ribose
Firm:	Leiner Health Products
Date Received by FDA:	January 21, 2000
90-day Date:	April 17, 2000

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 April 19, 2000.

Robert J. Moore, Ph.D.

95S-0316

RPT 63

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 24 2000

Hany Farag
Director of Regulatory Affairs
Leiner Health Products
901 East 233rd Street
Carson, California 90745-6204

Dear Mr. Farag:

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 January 18, 2000, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., D-Ribose) was received by the Food and Drug Administration (FDA) on January 21, 2000. Your submission will be kept confidential for 90 days from the date of receipt, and after April 19, 2000, 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,

Robert J. Moore

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements

LEINER
HEALTH PRODUCTS

901 E. 233rd Street
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90745-6204
310/835-8400
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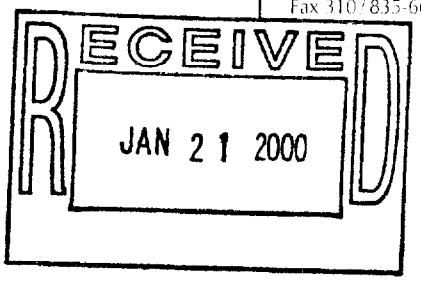

January 18, 2000

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

Re: Submission of 75 – Day Premarket Notification for New Dietary Ingredient.

Dear Sir or Madam:

In accordance with the requirements of section 8 of the Dietary Supplement Health and Education Act, Leiner Health Products is notifying the Food and Drug Administration that it will be marketing d-Ribose as a new dietary ingredient.

We take this action with the understanding that Leiner Health Products will not market this product for a period of at least 75 days after the FDA receipt of this notification.

Company Name and Address:

Leiner Health Products
901 E 233rd Street
Carson, CA 90745

Ingredient Name:

- D-Ribose

Description

There will be two dietary supplements containing the above-mentioned new dietary ingredient.

The first dietary supplement will be in powder form with a suggested use of 4 scoops of powder, (60 g) to be mixed as a drink. This 60 gram dose provides 12 grams of D-Ribose daily.

The second dietary supplement will be in tablet form with a suggested use of 1 tablet, three times daily. This three tablet maximum daily dose provides 3 grams of D-Ribose daily.

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January 18, 2000
Office of Special Nutritionals (HFS-450)
Center for Food and Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington DC 20204

Product Safety

Please find attached documentation, which establishes that the new dietary ingredient (D-Ribose) when taken under the suggested use is reasonably expected to be safe.

Respectfully Submitted,

Hany Farag,
Director of Regulatory Affairs