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OCT - 2 2000

Neil Blechman
Executive Vice President
Twin Laboratories, Inc.
150 Motor Parkway
Hauppauge, New York 11788

Dear Mr. Blechman:

This is in response to your letter of August 30, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Twin Laboratories, Inc. is making the following claim, among others, for the product **Twinlab NutraFlora®FOS**:

"...Harmful bacteria cannot utilize NutraFlora® FOS."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely, those caused by pathogenic microorganisms. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 396

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Please contact us if you require further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

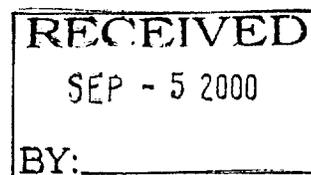
HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-811:afp:9/27/00:72261.:disc1

August 30, 2000

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



Dear Sir or Madam:

This letter will serve as 30-day notification, pursuant to section 403 (r)(6) of the Federal Food, Drug & Cosmetic Act and regulations promulgated thereunder.

Name and address of Dietary Supplement Manufacturer: Twin Laboratories, Inc.
150 Motor Parkway
Hauppauge, NY 11788

Text of statement being made: "Scientific research shows that NutraFlora® FOS selectively promotes the growth of beneficial and friendly bacteria, such as Lactobacillus acidophilus and bifidobacteria in the intestines. Harmful bacteria cannot utilize NutraFlora® FOS."

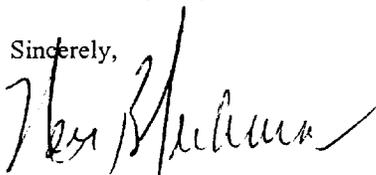
Dietary supplement ingredients: NutraFlora® (Fructooligosaccharides).

Dietary supplement brand and name: Twinlab NutraFlora® FOS.

As required, enclosed are two photocopies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Twin Laboratories, Inc., has substantiation that the statement is truthful and not misleading.

Sincerely,



Neil Blechman
Executive Vice President
Twin Laboratories, Inc.

Enclosures

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