

7904 '01 JUN 11 P2:05
MAY 16 2001

Dr. Stacey J. Bell
Chief Scientist
Functional Foods, Inc.
375 Concord Avenue
Belmont, Massachusetts 02478

Dear Dr. Bell:

This is in response to your letter of May 3, 2001 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 Functional Foods, Inc. is making the following claims for the product **Level Best**:

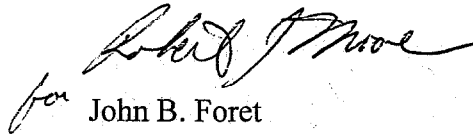
- “Helps maintain healthy blood sugar levels”
- “Helps maintain healthy blood cholesterol levels”
- “Helps maintain healthy blood clotting”

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 statements that you are making for this product suggest that it is intended to treat, prevent, cure, or mitigate diseases, namely, coronary heart disease, hypercholesterolemia, and disorders of blood glucose levels. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims 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.

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Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in cursive script, appearing to read "John B. Foret".

for 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 England District Office, Office of Compliance, HFR-NE240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:5/14/01:docname:75809.adv:disc57

Functional Foods
INC

75809

May 3, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Federal Building 8
200 C Street, S.W.
Washington, D.C. 20204

MAY 07 2001
TVBD

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, this letter provides notification that Functional Foods, Inc. has marketed a dietary supplement with the brand name "Level Best" with the following claims:

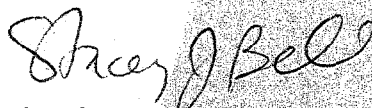
Helps maintain healthy blood sugar levels

Helps maintain healthy blood cholesterol levels

Helps maintain healthy blood clotting

The undersigned certifies that the information contained in this notification is complete and accurate that the company has substantiation that the statements are truthful and not misleading.

Sincerely yours,



Dr. Stacey J. Bell,
Chief Scientist