



7899 01 JUN 11 P2:04
MAY 15 2001

Ms. Laura Dufort
Vice President of Marketing
FreeLife
333 Quarry Road
Milford, Connecticut 06460

Dear Ms. Dufort:

This is in response to your letter of April 16, 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 FreeLife is making the following claims for the product Cholestesoy™:

“Promotes healthy cholesterol levels.”

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, cure, or mitigate disease, namely, hypercholesterolemia. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

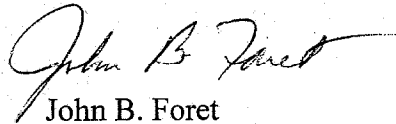
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Please contact us if we may be of further assistance.

Sincerely,



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)

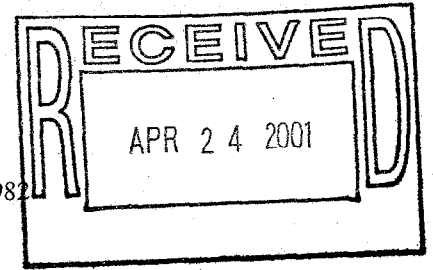
HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:5/7/01:docname:75625.adv:disc57



333 Quarry Road, Milford, CT 06460 Telephone: (203) 882-7250 FAX: (203) 874-4982



04/16/01

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

Re: Notification of Structure/Function Statement(s) for a Dietary Supplement

Dear Sir or Madam:

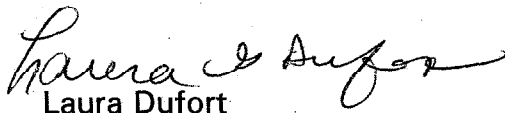
Pursuant to §403(r)(6) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §343(r)(6), and 21 CFR §101.93, the undersigned submits the following on behalf of FreeLife, LLC.

Structure/Function Statement:

Promotes healthy cholesterol levels

Name of Dietary Supplement: Cholestesoy™

I hereby certify that the information contained in this notification is complete and accurate, and that the above listed firm has substantiation that the statement is truthful and not misleading.


Laura Dufort
Vice President of Marketing

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