



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

1029 '01 APR 13 P3:21
MAR 19 2001

Ms. Margaret Edwards
Executive Administrator
Rainbow Light Nutritional Systems
125 McPherson Street
Santa Clara, California 95060

Dear Ms. Edwards:

This is in response to your letter to the Food and Drug Administration (FDA) dated January 11, 2001. In your letter, you stated that Rainbow Light Nutritional Systems disagrees with FDA's view that the claim constituted by the name of the product "Men's Heart Health" suggests that the product is intended to treat, prevent, cure, or mitigate disease. You stated that your label claim is a claim of the type permitted under Title 21 of the Code of Federal Regulations (21 CFR) Part 101.93(g)(2)(iv). You stated that the claim "Men's Heart Health" is not significantly different from the claims "Heart Tabs" and "Cardiohealth" described in the preamble language to the January 6, 2000 final rule (65 FR 1000 at 1022).

You are correct that FDA concluded that not all claims that consist of brand names that include the word "heart" or other organs are disease claims under the Federal Food, Drug, and Cosmetic Act (the Act). In the preamble to the final rule, FDA stated that it interpreted 21 CFR 101.14(a)(1) as permitting dietary supplements to have brand names that include the word "heart" or other organs, if, in the context of the labeling as a whole, the name does not imply disease treatment or prevention. We stated that a dietary supplement could be called, for example, "HeartTabs," if its claim was to "maintain healthy circulation," or some other role related to the structure or function of the heart that did not imply treatment or prevention of disease. We further stated that if, however, the product name was not qualified by any further claim in the labeling, the product could be considered, under 21 CFR 101.14(a)(1), to be intended for treatment or prevention of cardiovascular disease. Based on the information in your notification, there is no other information in the labeling of this product to qualify the claim "Men's Heart Health," and, therefore, it appears to be an implied claim to treat or prevent heart disease. For this reason, we are not persuaded that the conclusion expressed in our November 8, 2000 letter is incorrect and we stand by our original determination that the claim proposed in your original submission is a disease claim that subjects your product to regulation under the drug provisions of the Act.

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LET 467

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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:

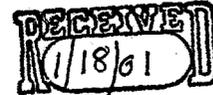
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Compliance Branch, HFR-PA140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Nickerson)
f/t:rjm:HFS-811:11/27/00:docname:shaklee.adv:disc52

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74091



January 11, 2001

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety and Applied Nutrition
200 "C" St., S.W. (HFS-450)
Washington, D.C. 20204

Dear Mr. Foret:

We are in receipt of your letter informing Rainbow Light Nutritional Systems that our product name, "Men's Heart Health," suggests that the product is intended to treat, prevent, or mitigate disease, namely coronary heart disease.

It is our understanding through advice from our regulatory advisors and our own review of the FDA's final regulation on structure/function claims that the new regulation permits label claims for general claims of this type. Section 101.93(g)(2)(iv) offers examples of acceptable names for products including "Cardiohealth" and "Heart Tabs," which are not significantly different from the phrase "Heart Health" used by Rainbow Light. We are aware of many other companies making similar claims with apparently no objections from the Agency.

It is our position that this product name is by no means a disease claim, as there is no implication of cardiovascular disease or related pathology. Rather, it is a product for men to support the overall health of the heart.

Sincerely,

A handwritten signature in cursive script that reads "Margaret Edwards". The ink is dark and the signature is fluid and legible.

Margaret Edwards
Executive Administrator

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PH: 831/429.9089 • 800/635.1233 • FAX: 831/429.0189

Rainbow Light Nutritional Systems • 125 McPherson St., Santa Cruz, California 95060 www.rainbowlight.com