



MAR 23 2000

3 2 8 7 '00 APR 25 P 2 :39

Mr. Wayne Reis
President
E'OLA International, Inc.
3879 South River Road
St. George, Utah 84790

Dear Mr. Reis:

This is in response to your letter of March 8, 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 E'OLA International, Inc. is making the following for the product **Cardio 180**:

“A unique combination of essential herbs and nutrients including commiphora, known for supporting normalized 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 diseases, 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.

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

975-0163

LET 352

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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, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

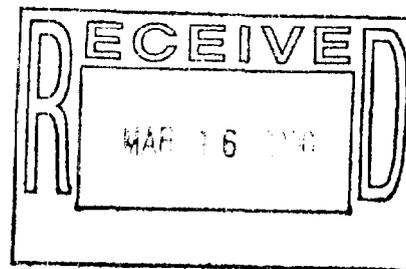
HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-811456:rjm:2/22/00:docname:69787.adv:disc45



March 8, 2000



Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, S.W.
Washington D.C. 20204

Re: Fulfillment of Reporting Obligation
Under 21 U.S.C. & 343® and 21 CFR & 101.93

Dear Dr. Yetley:

E'OLA International, in accordance with 21 U.S.C. & 343® and 21 CFR & 101.93, hereby submits an original and two copies of its notification of its product marketing with the statement presented below. E'OLA International retains scientific documents supporting the statements.

1. Supplement Brand Name: **Cardio 180**
2. Supplemental Ingredient(s) that is the subject of the statement: **Commiphora**
3. Text Of Statement Of Nutritional Support: **“A unique combination of essential herbs and nutrients including commiphora, known for supporting normalized cholesterol levels.”**

In accordance with 21 U.S.C. & 343® and 21 CFR & 101.93©, each of the above statements will be followed by an asterisk that will cross-reference to another asterisk on the very same panel or page next to which the following statement will appear in the box in bold face type: **“These statements have not been evaluated by the Food and Drug Administration. The product is not intended to diagnose, treat, cure or prevent any disease.”**

Respectfully Submitted,

Wayne Reis
E'OLA International, Inc.
President

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