



SEP 24 1999

6751 '99 SEP 29 02:29

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

Dear Mr. Reis:

This is in response to your letter of September 3, 1999 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 statement, among others, for the following products:

Cardio 180: "...known for its cholesterol lowering abilities"

E'proBalance: "...formulated to address the issues of PMS, post- and peri-menopause and bone density loss"

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 claims that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate a disease, namely, hypercholesterolemia and osteoporosis (i.e., bone density loss). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 302

Page 2 - Mr. Wayne Reis

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, Compliance Branch, HFR-S W240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0 163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file)

HFD-3 10 (B Williams)

HFD-3 14 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

HFV-229 (Benz)

GCF- 1 (Barnett, Nickerson, Dorsey)

f/t:rjm:HFS-456:9/16/99:67162.adv:disc40



September 3, 1999



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. & 3438 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: **E'proBalance**
2. Supplemental Ingredient(s) that is the subject of the statement: **Natural progesterone derived from wild yam**
3. Text of Statement of Nutritional Support: **"Take advantage of this remarkable product formulated to address the issues of PMS, post- and peri-menopause and bone density loss."**

In accordance with 21 U.S.C. & 343® and 21 CFR & 101.930, 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."**

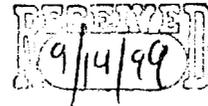
Respectfully Submitted,

Wayne Reiss
E'OLA international

67162



September 3, 1999



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. & 3438 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 its cholesterol lowering abilities.”**

In accordance with 21 U.S.C. & 343® and 21 CFR & 101.930, 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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