



OCT 30 2000

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

Rec'd 10/16/2000

Dear Mr. Reis:

This is in response to your letters of September 28, 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, is making the following claims, for the products below:

Aloe Min

"...strengthens and enhances the body's immune system, making it easier to fight off everyday common invaders."

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 these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. 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.

Calcimin

"...helping to prevent osteoporosis."

This statement is a claim of a relationship between calcium and osteoporosis. This statement is not a claim subject to 21 U.S. C. 343 (r)(6), but a claim subject to 21 U.S.C. 343 (r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis. A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U. S. C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR101.72 subjects the product to regulation as a drug under 21 U.S. C. 321 (g)(1)(B) because the product is intended to treat, cure prevent or mitigate a disease, osteoporosis.

978-0163

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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

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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-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-811:afp:10/19/00:72824:disc1



**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

This notification is being filed on behalf of E'OLA International which is the owner of the product which bear the statements identified in this notification. Its business address is: 3879 South River Road, St. George, UT. 84790. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is - **Calcimin**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "Calcium is essential for strong bones and great teeth, as well as a key component in helping to prevent osteoporosis."

The following summary identifies the supplement for which a statement has been made:

Statement	Identity of <u>Supplement that is the Subject of the Statement</u>
1.	Calcimin

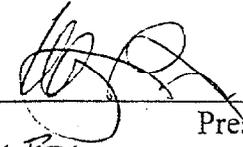
The following identifies the brand name of the each supplement for which a statement is made:

Statement Number	Brand Name
1	Calcimin

I, Wayne Reis, am authorized to certify this Notification on behalf of E'OLA International. I certify that the information presented and contained in this Notification is complete and accurate, and that E'OLA International has substantiation that each structure-function statement is truthful and not misleading.

Date Signed:

9/28/00 _____

By:  _____
Name: WAYNE REIS President



E'OLA[®]

NOTIFICATION PURSUANT TO INTERNATIONAL SECTION 6 OF DSHEA AND 21 CFR §101.93

This notification is being filed on behalf of E'OLA International which is the owner of the product which bear the statements identified in this notification. Its business address is: 3879 South River Road, St. George, UT. 84790. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is - **ALOE-MIN**.

The text of each structure-function statement for which notification is now being given is:

Statement 1: "It strengthens and enhances the body's immune system, making it easier to fight off everyday common invaders. In addition to its immune-enhancing abilities, the delicious fruit-flavored drink promotes normal tissue growth and repair."

The following summary identifies the supplement for which a statement has been made:

Statement Identity of Supplement that is the Subject of the Statement

1. Aloe Min

The following identifies the brand name of the each supplement for which a statement is made:

Statement Number	Brand Name
1	Aloe Min

I, Wayne Reis, am authorized to certify this Notification on behalf of E'OLA International. I certify that the information presented and contained in this Notification is complete and accurate, and that E'OLA International has substantiation that each structure-function statement is truthful and not misleading.

Date Signed:

9/28/00

By: _____

Name

WAYNE REIS

President