



IVAX Dermatologicals, Inc

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William H. Eaglstein, M.D.
President

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12/23/05

December 16, 2005

Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

**NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT**

The undersigned files this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6). The certification required by 21 C.F.R. § 101.93 (a)(3) is attached.

Brand Name: Heliocare®

Dietary Ingredients: Polypodium leucotomos (Calaguala) extract (leaf)

Statements of Nutritional Support:

Heliocare capsules, an oral dietary supplement with antioxidant properties which helps maintain the skin's ability to protect against sun-related effects and aging.

Fernblock™ works to protect skin structure and immune response and provides daily defense against the UV photoaging process. (Note: Fernblock™ is the standard Polypodium leucotomas extract contained in Heliocare® capsules.)

It acts as a scavenger to mop up free radicals and reactive oxygen species (ROS), particularly superoxide anions.

Inhibits formation of sunburn cells

Protects collagen by inhibiting the formation of MMP's

Protects DNA by inhibiting the formation of dimers

Antioxidant and immune response effects

2005-8604
Aims

Sincerely,
Ivax Dermatologicals, Inc.

By: William H. Eaglstein, M.D./President

Attachment - Certification

97S 0162

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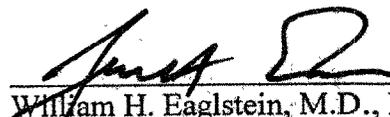
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21 C.F.R. § 101.93(a)(3) Certification

I certify that the information contained in the preceding section 403(r)(6) notice for Heliocare® is complete and accurate and that Ivax Dermatologicals, Inc. has substantiation that the statements are truthful and not misleading.


William H. Eaglstein, M.D., President
Ivax Dermatologicals, Inc.

December 16, 2005