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JUN - 5 2006

Barbara Levenstein
Director of New Product Development
Arkopharma, LLC
200 Research Drive
Wilmington, Massachusetts 01887

Dear Ms. Levenstein:

This is in response to your letter of May 12, 2006 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 stated that Arkopharma, LLC is promoting the product "Health From the Sun - ImmunoLyptus" to "Support Healthy Immune Function". In this context, it is also claimed that "Its primary actions are to promote clear, uncongested nasal passages and healthy bronchial function especially during the cold and flu season."

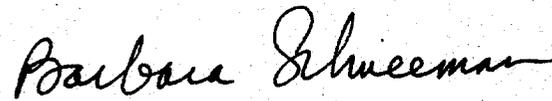
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, in light of their intended use during "cold and flu season," suggest that it is intended to treat, prevent, or mitigate diseases, namely the common cold and influenza. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in cursive script that reads "Barbara Schneeman".

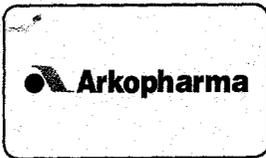
Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

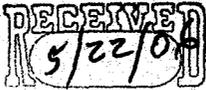


Celebrating
30 Years
1976-2006



May 12, 2006

Notification of statements on Dietary Supplement Labels



Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Food and Drug Administration
(HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Sir/Madam:

Reference is made to **ImmunoLyptus**, marketed by Arkopharma, LLC.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. 343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name: Health From The Sun – ImmunoLyptus
Ingredients: Eucalyptus Leaf Powder
Company Name/ Arkopharma, LLC
Address: 200 Research Drive, Unit 4
Wilmington, MA 01887

Text of Claims:

1. ImmunoLyptus provides specially prepared eucalyptus leaf powder to support the body's natural abilities to maintain health.
2. Its primary actions are to promote clear, uncongested nasal passages and healthy bronchial function especially during the cold and flu season.
3. Supports: Healthy Immune Function

In accordance with 21 CFR 101.93, the disclaimer statement is bolded and boxed on all panels of the label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma, LLC, has substantiation that the statements are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (781) 276-0505.

Sincerely,

Barbara Levenstein

Barbara Levenstein, M.S.
Director of New Product Development
Arkopharma, LLC

#1695

06-4644