



JUL 27 2001 8 52 16 AM AUG -8 P2 :21

Ms. Phyllis Tan
BMK International, Inc.
15 Lathrop Road
Wellesley, Massachusetts 02482

Dear Ms. Tan:

This is in response to your letter of June 1, 2001 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 BMK International, Inc. is making the following claims, among others, for the product **Neo-Concept® Aller Relief**:

“...airborne irritants...can clog the sinuses.”
“...Aller Relief...supporting clear and easy breathing.”
“Supports sinus.”

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, including use of the name of the product (i.e., Aller Relief,” suggest that it is intended to treat, prevent, cure, or mitigate diseases, namely, allergies. 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, 7520 Standish Place, Rockville, Maryland 20855.

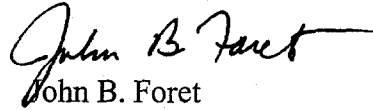
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Page 2 - Ms. Phyllis Tan

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

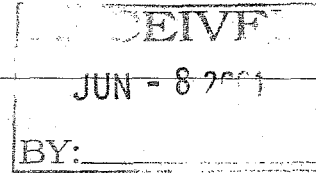
Copies:

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

BMK International Inc.
15 Lathrop Road • Wellesley, MA 02482 • Tel: (781) 235-9999



Office of Special Nutritionals (HFS-450)
Center for Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

76307

June 1, 2001

Dear Sir,

Please see enclosed the following information for the notification for Statements on Dietary Supplements.

We have enclosed one original and two copies.

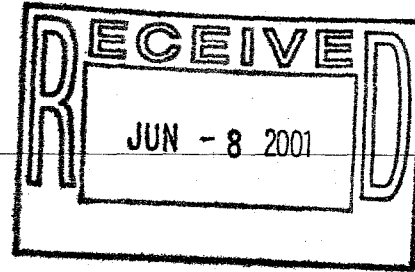
If you have any questions, please contact BMK at the following:

BMK International Inc.
15 Lathrop Road
Wellesley, MA 02482
Tel: (781) 235-9999

Thank you for your time and consideration.

Best Regards,

Phyllis Tan
Product Manager



Distributor:

BMK International Inc.
15 Lathrop Road
Wellesley, MA 02482

Text:

Aller Relief is a special Chinese formulation with Magnolia Flowers and other Chinese herbs. According to traditional Chinese herbalism, airborne irritants or wind cold can clog the sinuses. *Aller Relief* disperses wind cold, supporting clear and easy breathing. Supports sinus*

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any diseases.

Name of the ingredients:

Magnolia Flowers

Name of the supplement:

Neo•Concept® Aller Relief

A handwritten signature in black ink, appearing to read "Phyllis Tan", written over a horizontal line.

authorized signature

Phyllis Tan
Product Manager

76307