



FEB -2 2000

7 9 8 6 '00 FEB -8 P1 :59

Mr. David Gummer
Director of Marketing
Metabolife International, Inc.
5070 Santa Fe Street
San Diego, California 92109

Dear Mr. Gummer:

This is in response to your letter of January 31, 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 Metabolife International, Inc. is making the following claim, among others, for the product **Chinac™ Immune Health Formula**:

“Provides herbal support 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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely, the common cold and influenza. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

Please contact us if you require 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

975-0163

LET 334

Page 2 - Mr. David Gunner

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, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett)

f/t:HFS-456:rjm:2/1/00:docname:69035.adv:disc44



Metabolife

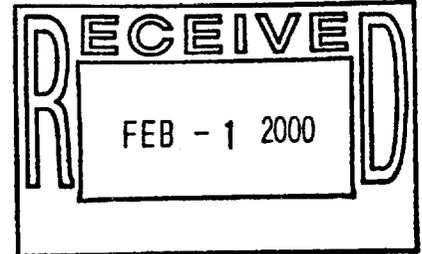
January 31, 2000

Metabolife International, Inc.
5070 Santa Fe Street
San Diego, California 92109

Telephone 858 490 5222

VIA FACSIMILE (202-205-5295) AND FIRST CLASS MAIL

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



Re. **Statement of Nutritional Support Notifications**

To Whom It May Concern:

We are hereby informing you that Metabolife International, Inc. ("Metabolife") has initiated the marketing of five new dietary supplement products that require the submission of notifications to the FDA under 21 C.F.R. § 101.93.

The first product, marketed under the trade name Chinac™ Immune Health Formula, contains the following herbal ingredients: Honeysuckle, Forsythia, Isatis, Astragalus, Chinese peony and Blackberry lily. The following labeling claims are made for the product:

- (1) provides herbal support during the cold and flu season
- (2) formulated to maintain Chi - enhancing your body's natural health-providing capabilities and supporting its inner balance.

The second product, marketed under the trade name Chinac™ Digestive Health Formula, contains the following herbal ingredients: Job's tears, Poria, Chinese hawthorn, Chinese anemum, Sweet wormwood, Xanthium, Rice and Apricot. The following labeling claims are made for the product:

- (1) formulated to help maintain proper stomach function
- (2) ideal for use with spicy or hard-to-digest foods
- (3) formulated to maintain Chi - supporting your body's natural ability to maintain its inner balance
- (4) stimulates Yang and help maintain easy and natural functions of the digestive organs.

The third product, marketed under the trade name Chinac™ Stress and Tension Formula, contains the following herbal ingredients: Burdock, Sichuan lovage, Corydalis yanhusuo, Fragrant angelica and Siler. The following labeling claims are made for the product:

- (1) supports the function of pain-mediating receptors in the head and neck
- (2) formulated to maintain Chi - enhancing your body's natural health-providing capabilities and maintaining inner balance.