

Los Angeles District  
1521 West Pico Boulevard  
Los Angeles, California 90015-2488  
Telephone: 213-688-3771

CERTIFIED - RETURN RECEIPT REQUESTED

July 15, 1992

NAF-53-2

NOTICE OF ADVERSE FINDINGS

Mark Hughes, General Partner  
Herbalife  
5741 Buckingham Heights Parkway  
Culver City, CA 90230

Dear Mr. Hughes:

We have reviewed the labeling included in your Herbalife Distributor Kit and on several of the products you distribute. These products are in violation of the Federal Food, Drug, and Cosmetic Act as follows:

1. "Slim and Trim Formula 2" appears to contain two herbal ingredients, mandrake and poke root, which have been considered as unsafe for food use. We also noted that "Slim and Trim Formula 4" is labeled as containing "Food Grade Linseed Oil". We question that such a substance actually exists. Linseed oil has not been considered an edible oil in the United States and use as a food additive is allowed only in a few designated instances. Consequently, we consider Slim and Trim Formulas 2 and 4 to be adulterated under 402(a)(1) of the Act.
2. Despite your disclaimers, we consider the therapeutic claims in the Herbalife Official Career Book ranging from arthritis to venereal disease, dissolves and removes tumors, and rejuvenating; the labeling claims to increase circulation and for mental alertness for "Herbalife Cell-U-Loss" and "NRG Natures Raw Guarana", respectively, as misbranding in that they falsely represent and suggest that these products are adequate and effective in providing the user of the products with treatment for or prevention of the labeled indications.
3. The substances lecithin, inositol, betaine, para-aminobenzoic acid, rutin, kelp, cider vinegar and uva ursi are not nutrients, may not be listed as nutrients, and the amounts should not be listed since this implies potency. The products which include declared amounts of such substances are Herbalife Slim and Trim Formula 2, Herbalife Slim and Trim Formula 3 and Herbalife Cell-U-Loss.

4. Vitamin E, phosphorus and zinc are in insignificant amounts to be called dietary supplements (generally at least 50% of the U.S. RDA) and therefore should only be listed in a complete ingredient statement in "Herbalife Slim and Trim Formula 3".
5. We believe the vignettes of athletes and references to "lift" on "NRG Natures Raw Guarana" falsely represents and suggests that this product will increase athletic ability.
6. The declaration of specific amino acids with analytical values such as on "Herbalife Slim and Trim Formula 1" are considered meaningless and misleading.

You should also be aware of the proposed warning label requirement for protein products which was published in the June 11, 1992 Federal Register (copy enclosed).

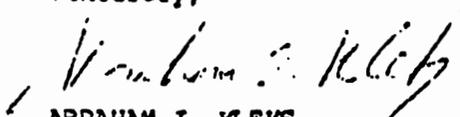
This letter is not meant to be all inclusive. It is your responsibility to ensure that all products distributed by your firm are in compliance with the provisions of the Federal Food, Drug, and Cosmetic Act.

Please advise us within thirty (30) days as to the specific actions taken or intended to be taken. In the case of future corrections an estimated date of completion should be included in your response to this letter.

Your response should be directed to:

Mr. Thomas L. Sawyer  
Director, Compliance Branch  
U.S. Food and Drug Administration  
1521 West Pico Boulevard  
Los Angeles, California 90015

Sincerely,

  
ABRAHAM I. KLEKS  
District Director

Encl: 6/11/92 Federal Register

bcc: HFA-224  
HFR-9200  
HFR-9250  
HFF-310  
✓ HFF File  
Chron File  
ET File