



W'w'ly- 10-30-89 HFI-35

October 26, 1989

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone 206-486-8788

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to: Regulatory Letter SEA 90-3

Stephen L. Welling, President
NaturPharma, Inc.
dba Nature's Herbs
1113 N. Industrial Park Drive
Orem, Utah 84057

REGULATORY LETTER

Dear Mr. Welling:

Investigations by the Food and Drug Administration reveal that you manufacture and label Ultra Trim Capsules for World Image Network, Inc., Boise, Idaho. This product is seriously misbranded under the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations (21 CFR) as follows:

SECTION

BRIEF DESCRIPTION

403(1)(1)
21 CFR 101.3(b)(3)

Ultra Trim is misbranded in that the label fails to bear an appropriately descriptive name of the vitamin composition of this dietary supplement of vitamins B6, C, and niacin.

403(j)
21 CFR 105.62,
105.66, and 105.69

Ultra Trim is misbranded in that the label fails to comply with the special dietary, hypoallergenic, caloric and sodium labeling required by the claim that the product is free of added yeast, dairy products, sugar, and salt.


We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this product. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 U.S.C. 332 and 334).

Stephen L. Welling, President
Page 2

In addition, we do not consider vitamin B3 as an appropriate synonym for niacin on the Ultra Trim label.

You may address your response to Donald E. Peterson, Compliance Officer, at this office.

Sincerely,


Roger L. Lowell
District Director

Enclosures:
FD&C Act
21 CFR 101 and 105

cc: 
