



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

REGULATORY LETTER

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 900
Telephone (213) 252-7583

November 15, 1988

Redgie B. Hansen, President
Above all Health, Inc.
7801 E. Gray Road, Suite #9
Scottsdale, Arizona 85260

LA-10-9

Dear Mr. Hansen:

During an investigation of your firm on August 17, 1988, Investigator Charles D. Moss documented that you are engaged in the distribution of germanium and evening primrose oil as food supplements. These articles, germanium and evening primrose oil, are in serious violation of the Federal Food, Drug and Cosmetic Act as follows:

SECTION

BRIEF DESCRIPTION

402(a)(2)(C)

The articles, capsules of evening primrose oil, tablets and capsules of germanium are adulterated within the meaning of Section 402(a)(2)(C) in that they are or contain unsafe food additives within the meaning of Section 409, because there are no regulations in effect pursuant to Section 409 prescribing the conditions under which these additives may be safely used and there is no exemption in effect for such use pursuant to Section 409.

We request that you take prompt action to correct these violations. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions such as seizure and/or injunction.

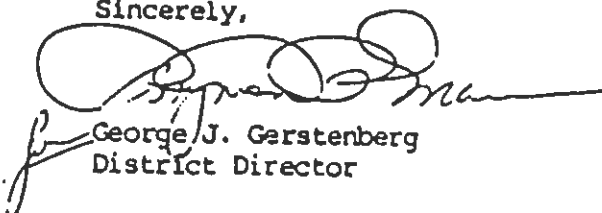
Please advise us in writing, within ten (10) calendar days of receipt of this letter, as to the steps taken to correct the violation and prevent its recurrence.

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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, CA 90015

Sincerely,



George J. Garstenberg
District Director

[REDACTED]

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