DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
50 United Nations Plaza, Room 526
San Francisco, California 94102
Telephone: 415-556-2062

September 19, 1991

Our Reference No. 29-50333

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Zane R. Kime, M.D.
Ameritron, Inc.
1212 High Street, Suite 204
Auburn, CA 95603

WARNING LETTER

Dear Dr. Kime:

Food and Drug Administration (FDA) examination of your Ameritron Micronutrients Tablets, Lot No. 1F80150693, six tablets per packet, revealed that the product is in serious violation of the Federal Food, Drug, and Cosmetic Act, as follows:

- Physico-chemical and microbiological assays indicated that the product contained no L-tryptophan, in contrast to label declaration that each packet of six tablets provided 100 mg of tryptophan. Consequently, the product is misbranded in accordance with Section 403(a) of the Act, in that its label is false.

- Ameritron Micronutrients Tablets is further misbranded, pursuant to Section 403(a), in that the "Statement of Purpose", which appears on its label, states that the product "prevent[s] the initiation and development of cancer" and "prevent[s] heart and vascular disease". Such statements, if continued, would render the product a drug, which is misbranded due to the lack of adequate directions for use. Moreover, references to the Secretary of Health and Human Services and to U.S. government regulations falsely imply that the product conforms to applicable laws and regulations.

- Ameritron Micronutrients Tablets is further misbranded, pursuant to Section 403(i), in that the common or usual name of the food, and of each ingredient, do not appear on the label.

- Ameritron Micronutrients Tablets is further misbranded, pursuant to Section 403(e)(2), in that an accurate statement of the quantity of the contents is not expressed on the label in terms specified by Title 21, *Code of Federal Regulations*, Part 101.105 (21 CFR).

- Where a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection between the person and the food: such as "Manufactured for _____", Distributed by _____", or any other wording that expresses the connection, as required

by 21 CFR 101.5(c)). Where no qualifying phrase is presented, the named person is presumed to be the manufacturer. Amerifron, Inc. is not the manufacturer but the distributor of Amerifron Micronutrients Tablets, and is not so qualified on the product label. The product is thereby misbranded pursuant to Section 403(e)(1) of the Act.

The misbranding of foods, while held for sale after shipment in interstate commerce, is prohibited under Section 301(k) of the Act. The introduction or delivery for introduction into interstate commerce of any food that is misbranded is prohibited under Section 301(a). Section 304 of the Act provides for seizure of misbranded food when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after introduction into interstate commerce.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure.

You should notify this office in writing, within fifteen (15) working days after receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, cite the reason for the delay and the time within which the corrections will be completed.

We also request information on the production of the protein hydrolyzate by your contract manufacturer. Tryptophan is destroyed during alkaline hydrolysis of proteins, thereby requiring the addition of tryptophan to compensate for the loss of protein quality. Additionally, the percentage of tryptophan in your product, in relation to the mix of amino acids, appears to be higher than normal.

As you may already know, the FDA, along with the Centers for Disease Control (CDC) and state and local health departments have been investigating reports of eosinophilia-myalgia associated with the consumption of non-prescription tablet, capsules and caplets of L-tryptophan.

CDC reports that, as of November 17, 1989, there were 287 reported cases of eosinophilia-myalgia syndrome associated with the ingestion of L-tryptophan tablets, capsules, and caplets. There are reports of four deaths being potentially associated with L-tryptophan associated eosinophilia-myalgia syndrome. The association of the remaining deaths with the consumption of L-tryptophan has not yet been confirmed and remains under investigation.

CDC reports that the epidemiological links between L-tryptophan consumption and eosinophilia-myalgia syndrome is unequivocal, and we support this conclusion. To date, FDA has been unable to determine the exact cause of the illness. It will be some time before the causative factors and the pathogenesis of the disease can be determine.

In this situation, we have no basis to believe that any single ingredient or major ingredient L-tryptophan tablet, capsule or caplet product is safe for

continued marketing.

We have strongly urged manufacturers, repackers, or distributors of over-the-counter products in which L-tryptophan is the sole or major component to recall, to the retail level, all distributed stocks of these products and to immediately cease production and distribution of the products.

Please direct your response to Mr. Fod Chu, Compliance Officer.

Sincerely,

/s/

David L. Chesney
District Director

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