April 11, 1990

REGULATORY LETTER

Certified Mail - Return Receipt Requested

Ronald D. Groll, Owner
Natural Nutrition
7301 Lansdowne
P.O. Box 13147
St. Louis, MO 63119

90-STL-013

Dear Mr. Groll:

We recently reviewed labeling for products that you offer for sale through your sales brochure (tabloid paper) and found them to be in serious violation of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

Section	Brief Description
601(e)	The Canthaxanthin tablets labeling claims the article has the ability to color the human skin a natural tan. The article is deemed to be adulterated in that it contains a color additive which is unsafe within the meaning of Section 706(a) of the Act.
402(a)(2)(c)	The Calcium Night Formula is deemed to be adulterated in that it contains magnesium orotate and calcium orotate, 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.
403(a)(1) [21 CFR 101.9(i)(5)]	The Calcium Night Formula is deemed to be misbranded in that its labeling is false and misleading since it lists horsetail herb, carrot acidophilus, spirulina, and bee pollen, substances which have no known nutritional value, in a manner which falsely implies that they have nutritional value.
403(i)(2)	The Calcium Night Formula is deemed to be misbranded since it is fabricated from two or more ingredients and its label fails to bear an ingredient statement as required by 21 CFR 101.4.

Please be advised that continued distribution of the adulterated articles is in violation of the Federal Food, Drug and Cosmetic Act.

We request that you respond in writing within 10 days of receipt of this letter delineating the steps you have taken or intend to take to ensure compliance. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions such as seizure and/or injunction.

Review of labeling for these articles does not constitute a comprehensive review of all the articles you offer for sale. It is your responsibility to ensure that the articles are correctly labeled and that advertising and/or sales literature properly reflect what the article is, how it is to be used, and that the article (including ingredients contained in it) can be marketed in accordance with the Federal Food, Drug, and Cosmetic Act.

Your response should be directed to Spencer L. Sorenson, Compliance Officer, at the address referenced in the letterhead.

Sincerely

Raymond K. Hedblad
Director
St. Louis Branch