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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

REGULATORY LETTER
91-DT-8

December 20, 1990

Jeffrey K. Farber, President
Michigan Pharmacal Corp.
3720 Lapeer Road
P.O. Box 57010
Auburn Hills, MI 48057

Dear Mr. Farber:

This letter is written with reference to Vibrant Health brand PROTEIN A High Protein Food with Lecithin & Amino Acids, 500 tablets marketed by your firm as a food for special dietary use.

We collected a sample of this product, lot 7610, and conducted a label review. Our review of the label has revealed that this product is in serious violation of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

<u>SECTION</u>	<u>BRIEF DESCRIPTION</u>
403(a)(1) 201(n)	The product is misbranded in that the label bears the claim "no xxx sodium" but lacks a declaration of sodium content as part of nutrition labeling.
403(i)(2)	The product is misbranded in that it is fabricated from two or more ingredients but its label fails to bear a listing of those ingredients by common or usual name in accordance with 21 CFR 101.4.

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

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Michigan Pharmacal Corp.

In addition, we have the following comments on the product label:

1. The nutrition labeling is not in the format and increments specified in 21 CFR 101.9. The nutrition information must be based on a serving of the food.
2. The identity statement for this food "A High Protein Food with Lecithin & Amino Acids" is not an appropriately descriptive term that describes the basic nature of this food or its characterizing properties. (21 CFR 101.3).
3. The nutrition information and name and place of business of the distributor do not appear on the information panel in accordance with 21 CFR 101.2.
4. This product label declares "High Protein". The product provides 12% of the U.S. RDA in three servings. No claim may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving. (21 CFR 101.9(c)(7)(v)).
5. It is not clear from the information supplied whether the suggested use is ten tablets per day or 30 tablets per day.

Please notify us in writing, within ten (10) days of your receipt of this letter, of the specific steps you have taken to correct these violations and prevent the recurrence of similar violations. If corrective action cannot be completed within ten days, please provide the reason for the delay and the time within which corrections will be completed.

Your response should be directed to this office to the attention of Ms. Sandra Williams, Compliance Officer.

Sincerely yours,

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off
12/24/80

CR

Carl C. Reynolds
District Director
Detroit District

