DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

March 23, 1999

Kirkpatrick W. Dilling
Dilling and Dilling Attorneys at Law
1120 Lee Road
Northbrook, IL 60062

re: Jason Vale
NYK-1999-5

Dear Mr. Dilling:

This responds to your December 16, 1998 and January 13, 1999 letters responding to the warning letter of October 28, 1998, we sent to your client, Christian Brothers, Whitestone NY.

The agency has completed its review of your response and has the following comments:

The agency's position is unchanged from that stated in the Warning Letter (e.g., that Vitamin B-17 also known as amygdalin, and also known as laetrile, is a drug, a new drug, and a misbranded drug).

- We remind you of the August 4, 1977 ruling of the US District Court for the Eastern District of Wisconsin that "amygdalin is a drug within the meaning of the Federal Food, Drug, and Cosmetic Act". The court further ruled that "Injectable amygdalin is *per se* a prescription drug ... amygdalin is not 'grandfathered' within the meaning of the Federal Food, Drug and Cosmetic Act." The court records indicate you were a counsel for the defendants in that case, and you should therefore be aware of this ruling.
- Injectable products are not permitted under the Dietary Supplements Health and Education Act (DSHEA) and are considered to be drug products by virtue of their route of administration.
- In addition, the label of the apricot seeds package, a product deemed to be a drug by virtue of the labeling applied by your client, lacks the address of the responsible firm and a declaration of the quantity of contents. This deficiency applies regardless of how the product is regarded, that is, it applies to the label on a package of a food, dietary supplement, drug, or any other product that we regulate.

Changes in the promotional literature and other labeling for these products should be made as soon as possible. Revised promotional literature and labeling (including, but not limited to, bottle labels, and cartons) should be submitted to the agency for evaluation to meet the conditions of the warning letter. Note that any "separate material" may also be considered as labeling whether it is shipped with the products or separately from the product.

ur reply relating to these matters should be directed to the Food and Drug Administration, Attention: William Friedrich, Compliance Officer, 850 Third Avenue, Brooklyn NY 11232.

Sincerely,

Brenda J. Holman
District Director
New York District