DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 28, 1998

Jason Vale
Christian Brothers
151-47 18th Avenue
Whitestone, NY 11357

re: NYK 1999-5

Dear Mr. Vale:

This letter is in reference to your promotion and distribution of the unapproved drug Laetrile in the form of your products "Apricot seeds", "Vitamin B-17 tablets", and "Amigdalina" ampules. Labeling for these products make therapeutic claims which cause the products to be drugs as defined in Section 201(g) of the Federal Food, Drug and Cosmetic Act. Labeling is not limited to the immediate product containers but includes all promotional material including video tapes which you distribute with your products.

According to your video, "World Without Cancer", these products represent different forms of "Vitamin B-17":

> "But in its [Vitamin B-17] concentrated and purified form developed by Dr. Krebs for cancer therapy, it's known as Laetrile. For the sake of clarity in this presentation, we shall favor the more simple name, Vitamin B-17."

Examples of the claims made for "Vitamin B-17" in the video tape titled "World Without Cancer" (which has your firm name, toll-free phone number, and website address clearly and prominently displayed) include:

- "The degree to which these people [Eskimos] are free from cancer is in direct proportion to the amount of nitrilosides or Vitamin B-17 found in their natural diets ... . Not one of these has ever been known to contract cancer";
- "The real cause of cancer is a vitamin and enzyme deficiency... Specific carcinogens do not cause cancer";
- "The reality of the Vitamin B-17 concept of cancer has been proven in the laboratory beyond doubt";

- "Today it's not uncommon to administer 2 or 3 grams in a single injection [of Laetrile]. Generally, 30-40 grams are required before the patient reports tangible signs of improvement";
- "What evidence to support that Laetrile works? The health records of Eskimos and other groups are statistically conclusive that B-17 does control cancer in human beings with effectiveness approaching 100%. There can be little controversy over that";
- "Can B-17 restore a person to health after he has contracted the disease? The answer is yes if it's caught in time and if the patient isn't too badly damaged by X-rays and toxic drugs. Unfortunately, most cancer victims start taking Laetrile only after their disease is so far advanced that they've been given up as hopeless by routine medical channels ... If they die, and many do, they are counted as statistical failures for Laetrile ... once a deficiency disease has progressed so far, the damage it has done simply can't be reversed ... A patient can have his cancer destroyed by B-17 and still die from the damage to his vital organs";
- "Of those who presently are healthy with no clinical cancer at all, close to one-hundred percent can expect to be free from cancer as long as they routinely obtain adequate amounts of vitamin B-17 and presuming they are not ... subjected to an unnatural exposure to carcinogenic agents such as massive radiation";
- "Once Vitamin B-17 is as widely understood and available as other vitamins, cancer will be as rare as scurvy or pellagra today. When nitrilosides are used perhaps as a routine seasoning to our food, like iodized table salt, then the battle [against cancer] will finally be won ... It's an objective that can be reached by anyone who acts on this knowledge. You and your family can now become secure from cancer."

These products are also "new drugs" [Section 201(p) of the Act] because there is no evidence that they are generally recognized as safe and effective for their intended uses. Since these products are "new drugs", they may not be marketed in the United States without approved new drug applications [Section 505(a) of the Act].

In addition, the book "World Without Cancer" establishes "intended use" for the products you promote. Your distribution of the book "World Without Cancer" establishes that the three products "Apricot Seeds", "Vitamin B-17" and "Amigdalina" (Laetrile) are intended for use in the prevention and treatment of cancer. Under 21 CFR 201.128, "intended use" is defined as "The objective intent of the persons legally responsible for the labeling of drugs".

"Apricot seeds", "Vitamin B-17" and "Amigdalina" (Laetrile) are also misbranded because their labeling fail to bear adequate directions for use [Section 502(f)(1) of the Act]; and are misbranded because their labeling are false and misleading in that the labeling suggests that the products are safe and effective for their intended uses, when this has not been established [Section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

Laetrile is still the object of Import Alert #62-01 and continues to be considered an unapproved new drug. In addition, Laetrile is not eligible for importation under the provisions of personal importation.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to William Friedrich, Compliance Officer; US Food and Drug Administration; New York District; 850 Third Avenue; Brooklyn, NY 11232. His telephone is 718/340-7000 extension 5532.

Sincerely,

Brenda J. Holman

Brenda J. Holman
District Director
New York District Office