



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";

