



Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

April 21, 1999

**WARNING LETTER
CIN-WL-99-171**

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. Perry Challender
Dealer/Advertiser
Something 4U
3599 Esquire Drive
Canal Winchester, OH 43110

Dear Mr. Challender:

This letter concerns your promotion of "Amigdalina/Vitamin B-17" tablets, "Amigdalina" ampules, and "Apricot seeds." While you do not distribute the products yourself, your promotion and activities associate you with the distribution of these products by others, specifically Christian Brothers. As a result, you are also responsible for the distribution of these products.

Labeling for these products make therapeutic claims which cause the products to be drugs [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 the video tape distributed with the Christian Brothers products. According to the 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 know as Laetrile. For the sake of clarity in this presentation, we shall favor the more simple name, Vitamin B-17."

The video also makes numerous disease claims for "Vitamin B-17" which 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”.

In addition, the book, “World Without Cancer”, establishes that the three products, “Apricot Seeds,” “Vitamin B-17,” and “Amigdalina” (Amygdalin), are intended for use in the prevention and treatment of cancer. “Intended use” is defined under CFR 201.128. These products are also “new drugs” [section 201(p) of the Act] and they may not be marketed legally in the United States without approved new drug applications [section 505(a) of the Act]. “Apricot seeds,” “Amigdalina/Vitamin B-17” tablets, and “Amigdalina” (Amygdalin) ampules are also misbranded [section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use and are false and misleading as it 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 you promote for Christian Brothers. It is your responsibility to ensure that all products you market and promote are in compliance with the Act and its implementing regulations.

Laetrile is 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.

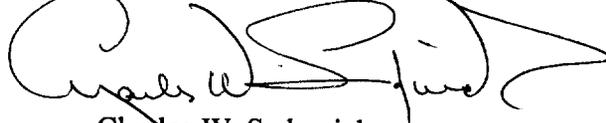
We request that you take prompt action to correct these violations. Failure to correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products.

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 occur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which you will implement corrections.

You should reply to Lawrence E. Boyd, Compliance Officer, US Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. His telephone number is (513) 679-2700, extension 167.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is fluid and cursive, with a large initial "C" and a long, sweeping tail.

Charles W. Sedgwick
Acting District Director
Cincinnati District Office

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