AO440 (Rev. 5/85) Summons in 8 Civil Action

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EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

CHRISTIAN BROS. CONTRACTING CORP., a corporation, and JASON VALE, an individual.

Defendants.

SUMMONS IN A CIVIL ACTION

CASE NUMBER:

TO: (Name and Address of Defena.n!)

Christian Bros. Contracting Corp
a corporation, and Jason Vale,
151-47 18th Avenue,
Whitestone, New York 11357

YOU ARE HEREBY SUMMONED and required to file with the Clerk of this Court and serve upon

PLAINTIFF'S ATTORNEY (name and Iddres<J

LORETTA E. LYNCH UNITED STATES ATTORNEY
One Pierrepont Plaza, Brooklyn NY, 11201
Attn: IgouM. Allbray, AUSA (718) 254-6002

an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint.

Robert C. Heinemann
ERK

November 24, 1999
DATE

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IA 1340

UNITED STATES OF AMERICA,

Plaintiff,

v.

CHRISTIAN BROS. CONTRACTING CORP., a corporation, and JASON VALE, an individual,

Defendants,

cv 99 7683

Civil Action No.

COMPLAINT FOR PERMANENT INJUNCTION.

The United States of America, plaintiff, by and through its undersigned counsel, respectfully represents to this Honorable Court as follows:

1. In this action for a statutory injunction brought pursuant to the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 332(a), plaintiff, the United States of America, seeks to permanently enjoin defendants Christian Bros. Contracting Corp., a corporation, and Jason Vale, an individual, from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355 (i);

b. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce drugs that are

misbranded within the meaning of 21 D.S.C. §§ 352 (c), 352 (f) (1), and 353 (b) (1) *i* and

c. 21 D.S.C. § 331(k), by causing drugs to become misbranded within the meaning of 21 D.S.C. §§ 352 (c), 352 (f) (1), and 353(b) (1) while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

2. This Court has jurisdiction over this action pursuant to 21 D.S.C. § 332(a), and 28 D.S.C. §§ 1331, 1337, and 1345.

3. Venue is proper in this District pursuant to 28 D.S.C. §§ 1391(b) and (c).

4. Defendant Christian Bros. Contracting Corp. (Christian Brothers) is a corporation organized and existing under the laws of the State of New York, and its principal place of business is 151-47 18th Avenue, Whitestone, New York, within the jurisdiction of this Court.

5. Defendant Jason Vale, an individual, is the president of Christian Brothers and has overall responsibility for, and authority over, all operations of the firm, including, but not limited to, the receipt, processing, packing, labeling, holding, and distribution of drug products. Mr. Vale performs his duties as president of Christian Brothers at the firm's Whitestone, New York place of business.

VIOLATIONS OF THE FDC ACT

6. Defendants have been and are engaged at 151-47 18th Avenue, Whitestone, New York, in receiving, packing, labeling, holding, and distributing in interstate commerce various products

made from or containing amygdalin (also known as Laetrile and "Vitamin B-17"), including injectable amygdalin, amygdalin tablets, and apricot seeds (hereinafter, "amygdalin products") Defendants' injectable amygdalin and amygdalin tablets are manufactured in Mexico.

7. Defendants' amygdalin products are drugs within the meaning of 21 D.S.C. § 321(g) (1)(B) because, as indicated in their labeling, in their promotional materials, and in statements by defendants and their employees, they are articles intended for use in the cure, mitigation, treatment, and prevention of human disease, namely cancer.

8. Defendants' drugs are new drugs within the meaning of 21 D.S.C. § 321(p) (1) because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

9. There is not now, nor has there ever been, an approved new drug application filed with the Dnited States Food and Drug Administration (FDA) pursuant to 21 D.S.C. § 355(b) or (j) for any of defendants' drugs. Further, defendants' drugs are not exempt under 21 D.S.C. § 355(i) from the premarket approval requirement. Therefore, defendants' amygdalin products are unapproved new drugs within the meaning of 21 D.S.C. § 355(a).

10. Defendants' drugs are misbranded within the meaning of 21 D.S.C. § 353(b) (1) in that they are drugs intended for use by

man which, because of the collateral measures necessary for their use, are not safe for use except under a physician's supervision, and they are dispensed without a prescription.

11. Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f) (1) because their labeling fails to bear adequate directions for use, and, because they are unapproved new drugs, they are not exempt from that requirement.

12. One of defendants' drugs, injectable amygdalin, is also misbranded under 21 U.S.C. § 352(c) in that information required by or under authority of the FDC Act to appear on the label or labeling is not in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use because it is written in Spanish.

13. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce unapproved new drugs in violation of 21 U.S.C. § 355, as set forth herein.

14. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce misbranded drugs, as set forth herein.

15. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of drugs held for sale after shipment in interstate commerce, as set forth herein.

16. FDA has documented defendants' distribution of amygdalin products in interstate commerce through undercover purchases from June 1998 to June 1999. Using fictitious names, FDA investigators placed three (3) orders with Christian Brothers

for various amygdalin products. In each case, Christian Brothers filled the orders by shipping the drugs in interstate commerce from New York to locations outside of New York. These shipments were received on or about June 18, 1998, January 19, 1999, and June 4, 1999. In each case, the amygdalin products were accompanied by written materials that promoted the drugs for the cure, mitigation, treatment, and prevention of cancer.

17. FDA ordered amygdalin products from Christian Brothers most recently on or bobout May 29,1999. An undercover investigator contacted Christian Brothers by telephone and subsequently sent the firm a written order for a "starter package" of amygdalin products. With his order, the investigator included a letter addressed to Christian Brothers stating in part: "I have kidney cancer and would appreciate it if you would ship the products quickly."

18. On or about June 4, 1999, the investigator received at a location in Pennsylvania the starter package of amygdalin products that he had ordered from the firm, which package included injectable amygdalin, amygdalin tablets, and apricot seeds. The package was postmarked as being sent from Whitestone, New York, and its return address was marked "Christian Brothers, 151-47 18th Avenue, Whitestone, New York 11357." Accompanying the "starter package" in this shipment were a product information sheet, a dosing information sheet, a videotape entitled "World Without Cancer," a book of the same name, and several pages of information compiled from the firmTs web sites, all of which

contained claims that amygdalin cures, mitigates, treats, and prevents all forms of cancer in humans.

PRIOR NOTICE

20. Defendants are well aware that their conduct is unlawful. Following FDA's first undercover purchase of amygdalin, FDA, in a Warning Letter dated October 28, 1998, informed defendants that their distribution of the amygdalin products violates the FDC Act. FDA repeated its warning by letter dated March 23, 1999. In spite of these warnings, defendants have distributed and continue to distribute unapproved new drugs and misbranded drugs in interstate commerce, in blatant disregard of the FDC Act.

21. In response to FDA's March 23, 1999 letter, by letter dated AprilS, 1999, defendants, through counsel, notified FDA that they no longer intended to sell injectable amygdalin. However, FDA's subsequent undercover purchase of that product in May-June 1999 demonstrates that defendants continue to distribute the drug product.

22. Plaintiff is informed and believes that, unless enjoined by this Court, defendants will continue to violate 21 D.S.C. §§ 331(a), (d), and (k) in the manner alleged herein.

WHEREFORE PLAINTIFF PRAYS:

1. That defendants, Christian Bros. Contracting Corp., a corporation, and Jason Vale, an individual, and each and all of their agents, representatives, employees, and attorneys, and any and all persons in active concert or participation with any of

them, be permanently enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, labeling, packing, processing, or distributing injectabl~ amygdalin, amygdalin tablets or apricot seeds; any similar product containing or purporting' to contain amygdalin, Laetrile, or Vitamin B-17; or any other drug product that is a "new drug" within the meaning of 21 D.S.C. § 321(p), unless and until:

1) an approved new drug application filed pursuant to 21 D.S.C. § 355 is in effect for such drug product; or

2) an investigational new drug application filed pursuant to 21 D.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug product, and the drug product is distributed and used solely for the purpose of conducting clinical investigations in accordance with the investigational new drug application;

B. Promoting, advertising, or representing that amygdalin, Laetrile, Vitamin B-17, or apricot seeds, or any other product containing or purporting to contain amygdalin, Laetrile, Vitamin B-17, or apricot seeds is safe and/or effective in the cure, mitigation, treatment, or prevention of any disease, unless and until an approved new drug application authorizing such representations is in effect for such product;

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c. Introducing or delivering for introduction into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. §§ 352(c), 352 (f) (1), or 353 (b) (1); and

D. Packing, labeling, or holding for sale any drug in any manner that causes such drug to become misbranded within the meaning of 21 U.S.C. §§ 352 (c), 352 (f) (1), or 353 (b) (1) while it is held for sale after shipment of one or more of its components in interstate commerce.

II. That FDA be authorized pursuant to this injunction to inspect defendants' place of business, facilities, and all records relating to the receipt, packing, labeling, holding, and distribution of any drug, including components, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by defendants at the rates prevailing at the time the inspections are performed.

III. That the Court grant plaintiff its costs and such other relief as the Court deems just and proper.

Dated this day of 1999.

Respectfully submitted,

LORETTA E. LYNCH
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