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

UNITED STATES OF AMERICA, Plaintiff, v. CHRISTIAN BROS. CONTRACTING CORP., a corporation, and JASON VALE, an individual, Defendants.	)	Civil Action No.99CV7683 CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, plaintiff, having filed a Complaint for Permanent Injunction against defendants Christian Bros. Contracting Corp., a corporation, and Jason Vale, an individual, and the defendants having appeared and having consented to the entry of this Decree, without admitting or denying any liability, and before any testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter of this action, and has personal jurisdiction over all parties to this action.

2. The Complaint for Injunction states a cause of action against the defendants under the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. §§ 301-97.

3. Defendants and each and all of their agents, representatives, employees, successors and assigns, and any and

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all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are hereby permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a), 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, processing, packing, labeling, promoting in violation of the FDC Act, or distributing amygdalin, laetrile, "Vitamin B-17", apricot seeds, any similar product containing or purporting to contain amygdalin, laetrile, "Vitamin B-17," or apricot seeds, or any drug product that is a new drug, as defined in 21 U.S.C. § 321(p), unless and until:

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

(2) an investigational new drug application filed pursuant to 21 U.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. 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).

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C. Causing the misbranding, within the meaning of 21 U.S.C. §§ 352(c), 352(f)(1), or 353(b)(1), of any drug while held for sale after shipment in interstate commerce.

4. All products containing or purporting to contain amygdalin, laetrile, "Vitamin B-17", or apricot seeds that are in the possession, custody, or control of defendants as of the date of entry of this Decree shall be destroyed at defendants' expense and under supervision of the U.S. Food and Drug Administration (FDA).

5. Duly authorized representatives of the FDA shall, at reasonable times and in a reasonable manner, be permitted, as FDA deems necessary and without prior notice, to make inspections of defendants' facilities, and all equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein, to take photographs and to examine and copy all records relating to the receipt, packing, labeling, promotion and distribution of any of defendants' products to ensure continuing compliance with the terms of this Decree. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. Such inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the FDC Act, 21 U.S.C. § 374.

6. Upon written notification from FDA, defendants shall immediately cease and discontinue receiving, packing, labeling,

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holding, and distributing any article determined by FDA to be intended for the cure, mitigation, treatment or prevention of disease or articles (other than food) intended to affect the structure or any function of the body of man or other animals, if FDA notifies the defendants in writing that their receiving, packing, labeling, holding, or distributing of such article is in violation of this Decree or the FDC Act. Any such cessation of operations shall go into effect without further order from this Court and, defendants shall not resume receiving, packing, labeling, holding, or distributing the article(s) that are the subject of FDA's notification until FDA notifies defendants in writing that defendants appear to be in compliance with the FDC Act and the requirements of this Decree.

7. Upon written notification from FDA, defendants shall institute recalls or take any other action(s) as FDA deems necessary or appropriate to ensure that the articles defendants receive, pack, label, hold, and distribute, or have received, packed, labeled, held, or distributed, are in compliance with the FDC Act. Any such recall shall be conducted by defendants in accordance with the recall procedures set forth in 21 C.F.R. Part 7. All costs of recalls, including the FDA supervisory costs, shall be borne by defendants in accordance with ¶ 8.

8. Defendants shall pay the costs of all inspections, supervision, reviews, examinations, and analyses conducted pursuant to this Decree at the standard rates prevailing at the

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time these activities are performed. As of the date of this Decree, the standard rates are as follows: $57.08 per hour or fraction thereof per representative for inspection work; $68.42 per hour or fraction thereof per representative for analytical work; $0.31 per mile for travel expenses; and $205.00 per day for subsistence expenses. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be adjusted accordingly without further order of the Court.

9. Should plaintiff bring, and prevail in, a civil or criminal contempt action arising out of a violation of the terms of this Decree, defendants shall, in addition to other remedies, reimburse plaintiff for attorneys' fees, expert witness fees, investigational expenses, travel expenses incurred by witnesses, administrative and court costs, and any other costs or fees related to such enforcement proceedings. However, should defendants prevail, nothing in this consent decree shall prohibit the defendants from seeking an award under the Equal Access to Justice Act.

10. Within ten (10) days of the date of entry of this Decree, defendants shall serve a copy of this Decree upon each of their agents, representatives, employees, successors and assigns, and upon any and all persons in active concert or participation with any of them.

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11. Within ten (10) days of the date of entry of this Decree, defendants shall post a copy of this Decree in all of the employee common areas at all of their facilities, and shall ensure that the Decree remains posted for a period of no less than six (6) months. Within thirty (30) days of the date of entry of this Decree, defendants shall provide to FDA and to plaintiff's attorneys an affidavit of compliance stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons upon whom this Decree has been served.

12. Defendants shall notify FDA in writing, at least twenty (20) days before any change in ownership, character, or name of their business, including reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, or any other change in the structure or identity of such business, or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assign within twenty (20) days prior to such sale or change in business, and shall furnish FDA and plaintiff's attorneys with an affidavit of compliance with this paragraph within fifteen (15) days prior to such sale or change in business.

13. Defendants shall address all communications with FDA required under this Decree to the Director, New York District

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Office, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433, and shall reference this case by name and civil action number in such communications.

14. All decisions conferred upon FDA in this Decree shall be vested in the discretion of FDA, subject to review, if necessary, by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A).

15. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be hereafter necessary or appropriate.

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16. Except as otherwise provided in this consent decree, the parties shall bear their own costs, including attorneys' fees, of this action and for compliance with this Decree.

IT IS SO ORDERED:

Dated: This 16th day of November, 2000.

John Gleeson
United States District Judge

A TRUE COPY
ATTEST
DATED 11/14 20 00
ROBERT C. HEINEMANN
CLERK
BY MG
DEPUTY CLERK

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We hereby consent to the foregoing decree.

JASON VALE, President, for
defendant CHRISTIAN BROS.
CONTRACTING CORP.

JASON VALE, Individually

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AFFIDAVIT OF MAILING

STATE OF NEW YORK
COUNTY OF KINGS
EASTERN DISTRICT OF NEW YORK, ss:

_____, being duly sworn, says that on the _____ day of _____, I deposited in Mail Chute Drop for mailing in the U.S. Courthouse, Cadman Plaza East, Borough of Brooklyn, County of Kings, City and State of New York, a _____ _____ of which the annexed is a true copy, contained in a securely enclosed postpaid wrapper directed to the person hereafter named, at the place and address stated below:

_____

_____

_____

Sworn to before me this
day of

_____

_____

AFFIDAVIT OF PERSONAL SERVICES

STATE OF NEW YORK
COUNTY OF KINGS
EASTERN DISTRICT OF NEW YORK, ss:

_____, being duly sworn, says that he is employed in the office of the United States Attorney for the Eastern District of New York. That on the _____ day of _____, he served a true copy of the annexed _____ on the office of attorney for _____ herein, located at _____, Borough of _____, City of New York, by leaving a true copy of same with his clerk or other person in charge of said office.

_____

Sworn to before me this
day of

_____

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Form No. USA-52a-6a
(Rev. 7/82)