## UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

**COMMISSIONERS:** Jon Leibowitz, Chairman

Pamela Jones Harbour William E. Kovacic J. Thomas Rosch

In the Matter of

DANIEL CHAPTER ONE,
a corporation, and
DOCKET NO. 9329

JAMES FEIJO,
individually, and as an officer of
Daniel Chapter One

DOCKET NO. 9329

## **FINAL ORDER**

The Commission has heard this matter on the appeal of Respondents from the Initial Decision and on briefs and oral argument in support of and in opposition to the appeal. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to enter the following order. Accordingly,

I.

**IT IS HEREBY ORDERED** that for purposes of this Order, the following definitions shall apply:

- A. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- B. "Covered Product or Service" shall mean any dietary supplement, food, drug, or other health-related product, service, or program, including, but not limited to, BioShark, 7 Herb Formula, GDU, and BioMixx.
- C. "Food" and "drug" shall mean "food" and "drug" as defined in Section 15 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 55.

- D. "Advertisement" means any written or verbal statement, illustration, or depiction that is designed to effect a sale or to create interest in the purchasing of goods or services, whether it appears in a book, brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, video news release, audio program transmitted over a telephone system, infomercial, the Internet, e-mail, or in any other medium.
- E. Unless otherwise specified, "Respondents" shall mean Daniel Chapter One and its successors and assigns, affiliates, or subsidiaries, and its officer, James Feijo, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.
  - F. "Commerce" shall mean "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
  - G. "Endorsement" shall mean "endorsement" as defined in 16 C.F.R. § 255.0(b).

II.

IT IS HEREBY ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of BioShark, 7 Herb Formula, GDU, and BioMixx, or any substantially similar health-related program, service, or product, or any other Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product or program names or endorsements, that such health-related program, service, product, or Covered Product or Service prevents, treats, or cures or assists in the prevention, treatment, or cure of any type of tumor or cancer, including but not limited to representations that:

- 1. BioShark inhibits tumor growth;
- 2. BioShark is effective in the treatment of cancer;
- 3. 7 Herb Formula is effective in the treatment or cure of cancer;
- 4. 7 Herb Formula inhibits tumor formation;
- 5. GDU eliminates tumors;
- 6. GDU is effective in the treatment of cancer;
- 7. BioMixx is effective in the treatment of cancer; or
- 8. BioMixx heals the destructive effects of radiation or chemotherapy;

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IT IS FURTHER ORDERED that Respondents, directly or through any person, corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

#### IT IS FURTHER ORDERED that:

- A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

#### **IT IS FURTHER ORDERED** that:

- A. Respondents shall, within seven (7) days after the date of service of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased BioShark, 7 Herb Formula, GDU, and/or BioMixx, on or after January 1, 2005 through the date of service of this order. Such list shall include each consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;
- B. Within forty-five (45) days after the date of service of this order, Respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part V.A., above. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and
- C. Except as provided in this order, Respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise

disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any Respondent, at any time prior to the issuance of this order, in connection with the purchase of BioShark, 7 Herb Formula, GDU, and/or BioMixx. *Provided, however*, that Respondents may disclose such identifying information to the FTC pursuant to Part V.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

#### VI.

**IT IS FURTHER ORDERED** that for a period of five (5) years after the last date of dissemination of any representation covered by this order, Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

#### VII.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

## VIII.

IT IS FURTHER ORDERED that Respondent Feijo, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include the individual Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IT IS FURTHER ORDERED that Respondent DCO and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. **Provided, however**, that, with respect to any proposed change in the corporation about which Respondent DCO learns less than thirty (30) days prior to the date such action is to take place, Respondent DCO shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

**IT IS FURTHER ORDERED** that Respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

#### XI.

IT IS FURTHER ORDERED that this order will terminate on December 18, 2029, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; **provided**, **however**, that the filing of such a complaint will not affect the duration of:

- A. Any paragraph in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

**Provided further,** that if such complaint is dismissed or a federal court rules that the Respondents did not violate any provision of this order, and the dismissal is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark Secretary

SEAL:

ISSUED: December 18, 2009

# ATTACHMENT A LETTER TO BE SENT BY FIRST CLASS MAIL

[To be printed on letterhead of Daniel Chapter One]

[Name and address of recipient] [Date]

Dear [Recipient]:

Our records show that you bought [names of products] from our website [name of website] or through a call center using our toll-free number. We are writing to tell you that the Federal Trade Commission ("FTC") has found our advertising claims for these products to be deceptive because they were not substantiated by competent and reliable scientific evidence, and the FTC has issued an Order prohibiting us from making these claims in the future.

The Order entered against us by the FTC requires that we send you the following information from the FTC about the scientific evidence on these products:

Competent and reliable scientific evidence does not demonstrate that any of the ingredients in BioShark, 7 Herb Formula, GDU or BioMixx, are effective when used for prevention, treatment or cure of cancer.

It is important that you talk to your doctor or health care provider before using any herbal product in order to ensure that all aspects of your medical treatment work together. Some herbal products may interfere or affect your cancer or other medical treatment, may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines, or in high doses. It is also important that you talk to your doctor or health care provider before you decide to take any herbal product instead of taking cancer treatments that have been scientifically proven to be safe and effective in humans.

Sincerely,

## ATTACHMENT B

Daniel Chapter One 1028 East Main Road Portsmouth, Rhode Island, 02871

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE