IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. BROWNWOOD ACRES FOODS, INC., and CHERRY CAPITAL SERVICES, INC. d.b.a. FLAVONOID SCIENCES, corporations, and STEPHEN C. de TAR and ROBERT L. UNDERWOOD, individuals, Defendants.	)	CIVIL NO. **1:08-cv-148** HON. **Paul L Maloney** **US District Judge** **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, United States of America, having commenced this action by filing its Complaint for Permanent Injunction, and Brownwood Acres Foods, Inc. ("Brownwood Acres") and Cherry Capital Services, Inc., d.b.a. Flavonoid Sciences ("Cherry Capital"), corporations, and Stephen C. de Tar and Robert L. Underwood, individuals (hereafter collectively, "Defendants"), having appeared and consented to the entry of this Decree without contest and before any testimony was taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

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 Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

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

4. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

5. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce food that is misbranded within the meaning of 21 U.S.C. § 343(r)(1)(B).

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product unless and until:

A. An approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(a) or (j) is effective with respect to the product; or

B. An effective investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

C. The product's claims comport with an authorized health claim set forth in 21 C.F.R. § 101.72-101.83; or

D. Defendants have received a letter of enforcement discretion for a qualified health claim from FDA for that product; or

E. Defendants have:

(i) removed all claims from Defendants' product labels, labeling, promotional materials, websites owned or controlled by Defendants, and in any other media that cause that product to be a drug and/or contain unapproved or unauthorized health claims within the meaning of the Act; and

(ii) removed, from their product labels, labeling, promotional materials, and websites owned or controlled by Defendants, references to or endorsements of any other website that conveys information about Defendants' products that cause those products to be a drug and/or contain unapproved or unauthorized health claims within the meaning of the Act.

7. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who receive actual

notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered 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. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce food that is misbranded within the meaning of 21 U.S.C. § 343(r)(1)(B).

8. Within ten (10) calendar days of FDA's request for any labels, labeling, promotional materials, and/or downloaded copies (on CD-Rom) of any internet websites owned or controlled by Defendants or websites referenced by, endorsed, or adopted directly or indirectly by Defendants, Defendants shall submit a copy of the requested materials to FDA at the address specified in paragraph 19.

9. Within twenty (20) calendar days of entry of this Decree, Defendants shall submit to FDA a certification of compliance, signed by each of the individually-named Defendants in this matter, each Defendant stating that he: (a) has personally reviewed

all of Defendants' product labels, labeling, promotional materials, and the internet websites referred to in paragraph 8 above; and (b) personally certifies that the product labels, labeling, promotional materials, and internet websites strictly comply with the requirements of the Act and its regulations and do not include unapproved or unauthorized claims that the products cure, mitigate, treat, prevent and/or reduce the risk of disease. Thereafter, Defendants shall submit certifications of compliance every three (3) months for a period of two (2) years.

10. Within fourteen (14) calendar days of entry of this Decree, Defendants shall retain an independent person or persons (the "expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training is qualified to assess Defendants' compliance with the Act, to review the claims Defendants make for all of their products on their product labels, labeling, promotional material, any internet websites owned or controlled by Defendants, including, but not limited to, the websites referred to in paragraph 8 above. At the conclusion of the expert's review, the expert shall prepare a written report analyzing whether Defendants are operating in compliance with the Act and in particular, certify whether Defendants have omitted all claims from their product labels, labeling, promotional materials, websites owned or controlled by Defendants, and in any other media, that make any of their products drugs and/or constitute unapproved or unauthorized health claims within the meaning of the Act. The expert shall also review Defendants' product labels, labeling, promotional materials, and websites owned or controlled by Defendants to determine whether these include any references to or endorsements of any other

websites that convey information about Defendants' products that cause those products to be a drug and/or contain unapproved or unauthorized health claims within the meaning of the Act, and certify in the written report whether Defendants have omitted any such references or endorsements. The expert shall submit this report to FDA and Defendants within thirty-five (35) calendar days of the entry of this Decree. If the expert reports any violations of the Act, Defendants shall, within seven (7) calendar days of receipt of the report, correct those deviations, unless FDA notifies Defendants that a shorter time period is necessary.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of Defendants' product labels, labeling, promotional materials, websites owned or controlled by Defendants, or websites referenced by, endorsed, or adopted directly or indirectly by Defendants that convey information about Defendants' products, a report prepared by Defendants' expert, or any other information, that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, or this Decree, FDA may, as and when it deems necessary, direct Defendants, in writing, to take one or more of the actions:

A. Cease manufacturing, processing, packing, labeling, holding, and/or distributing any article(s);

B. Submit additional reports or information to FDA;

C. Recall any article(s) at Defendants' expense; or

D. Take any other reasonable corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and this Decree.

12. Any cessation of operations as described above shall continue until FDA notifies Defendants in writing that Defendants appear to be in compliance with the Act and the requirements of this Decree, and that Defendants may resume operations. Such notification by FDA may not be unreasonably delayed.

13. Duly authorized representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted prompt access to buildings, equipment, in-process and finished materials, containers, labeling and other materials therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labels, labeling, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, promoting, holding, and distribution of any and all Defendants' products in order to ensure continuing compliance with the terms of this Decree. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

14. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree. For the purposes of this Decree, inspections include FDA's review and

analysis of Defendants' claims for their products in the product labels, labeling, promotional materials, any and all websites owned or controlled by Defendants, and any and all websites referenced by, endorsed, or adopted directly or indirectly by Defendants that convey information about Defendants' products. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $78.09 per hour and fraction thereof per representative for inspection work; $93.61 per hour or fraction thereof per representative for analytical or review work; $0.485 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

15. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including "doing business as" entities) (hereafter collectively referred to as "associated persons"). Within thirty-five (35) calendar days of the date of entry of this Decree, Defendants shall provide to FDA 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 associated persons who

have received a copy of this Decree and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Decree, with new associated persons, Defendants shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Decree to each such associated person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

16. Within ten (10) calendar days of entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in a common area at any of their manufacturing or distribution facilities, and shall ensure that the Decree remains posted for a period of twelve (12) months at each location.

17. Within ten (10) calendar days of entry of this Decree, Defendants shall provide FDA a list of all domain names and IP addresses they use to market or describe any product, regardless of whether such sites mention specific products Defendants sell. Defendants thereafter shall notify FDA within ten (10) days of any change to this list (either additions or deletions).

18. Defendants shall notify the District Director, FDA Detroit District Office, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in the corporate structure of Defendants Brownwood Acres or Cherry Capital, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree

to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

19. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, FDA Detroit District Office, 300 River Place, Suite 5900, Detroit, Michigan 48207.

20. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendants Brownwood Acres and/or Cherry Capital shall pay to the United States of America the sum of one thousand dollars ($1,000) in liquidated damages per violation per day so long as such violation continues. For the purposes of this paragraph, a "violation" is defined as each time any Defendant introduces or delivers for introduction into interstate commerce any product that is accompanied by (on the product's label, labeling, promotional materials, websites owned or controlled by Defendants, or in any other media) a claim(s) that causes the product to be a drug or constitutes a health claim within the meaning of the Act, unless the product is an approved new drug or such claim is authorized by FDA.

21. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

22. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

23. If, in FDA's judgment, Defendants maintain a continuous state of compliance with this Decree and the Act for a period of three (3) years after the date of entry of this Decree, and FDA has not notified Defendants that there has been a significant violation of this Decree or the Act during such time, the government will not oppose Defendants' petition to the Court to dissolve the Decree.

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

IT IS SO ORDERED:

Dated this ____ day of _____, 2008.

_____
UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR DEFENDANTS

STEPHEN C. DE TAR, on behalf of
Brownwood Acres Foods, Inc.
and Cherry Capital Services,
Inc., and Individually

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