IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIV-06:20-CV-00140-RAW**
	)	
	)	
XEPHYR LLC d/b/a N-ERGETICS, a corporation, and DERRILL JINKS FUSSELL a/k/a DERILL J. FUSSELL a/k/a BRAD BRAND and LINDA SUE FUSSELL a/k/a LINDA FUSSELL, individuals,	)	
	)	
Defendants.	)	

ORDER OF PERMANENT INJUNCTION

Plaintiff United States of America, having filed a Complaint for Preliminary and Permanent Injunction against Defendants Xephyr LLC doing business as N-Ergetics, and, as the caption was amended on August 11, 2020, Defendants Derrill Jinks Fussell a/k/a Derill J. Fussell a/k/a Brad Brand, and Linda Sue Fussell a/k/a Linda Fussell, and a motion for default judgment under Federal Rule of Civil Procedure ("Rule") 55(b)(2) as to Defendants; and no argument, evidence, or opposition having been submitted thereto; and it appearing that Defendants violated the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.*, and, unless restrained by order of this Court, will continue to violate the Act; it is

ORDERED, ADJUDGED, AND DECREED that:

1. The United States' motion for default judgment is **GRANTED**.

2. **DEFAULT JUDGMENT IS ENTERED** against Defendants.

3. This Court has jurisdiction over the subject matter and all the parties to this action.

4. The Complaint states a cause of action against Defendants under the Act, 21 U.S.C. §§ 301 et seq.

5. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce new drugs (as defined by 21 U.S.C. § 321(p)) that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt.

6. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug (as defined by 21 U.S.C. § 321(g)(1)) that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions for use.

7. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) while such articles are held for sale after shipment of one or more of their components in interstate commerce.

8. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them, who have received actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, manufacturing, preparing, packing, labeling, holding, or distributing any articles of drug, at or from 303 W. 12th Street, Atoka, Oklahoma, 74525 and 339 W. 12th Street, Atoka, Oklahoma, 74525, or at or from any other location(s) at which Defendants now or in the future

directly or indirectly receive, manufacture, prepare, pack, label, hold, or distribute articles of drug (hereafter, the "Facility"), unless and until:

A. For all of Defendants' drugs, Defendants have an approved new drug application ("NDA") or an abbreviated new drug application ("ANDA"), pursuant to 21 U.S.C. § 355(b), (j), or an investigational new drug application ("IND") in effect pursuant to 21 U.S.C. § 355(i), for such drugs;

B. Within six (6) business days after the entry of this Order, Defendants submit to FDA for its review and approval a recall plan for their colloidal silver products that were distributed to consumers from January 22, 2020, through and including the date of entry of this Order. The recall plan shall be submitted to FDA's Office of Regulatory Affairs / Office of Pharmaceutical Quality Operations Pharm II Recall Coordinator at orapharm2recalls@fda.hhs.gov and shall include, but not be limited to, customer notifications, public warning, methods for conducting effectiveness checks, and plans for the disposition of recalled products. Defendants shall promptly implement any changes that FDA directs in such plan. Within six (6) business days after receiving FDA's approval of the recall plan, Defendants shall initiate a recall of their colloidal silver products in accordance with the approved recall plan. Within twenty-two (22) business days after initiating the recall, Defendants shall complete the recall. Defendants shall bear the costs of the recall. Defendants shall destroy the recalled products and all their colloidal silver products, including components and raw and in-process materials and finished product, in Defendants' possession, custody, or control in accordance with the procedures provided in Paragraph 9;

C. As FDA determines it to be necessary, FDA representatives inspect Defendants' Facility, including buildings, equipment, products, labeling, and all relevant records

contained therein; and/or Defendants' product labels; labeling; promotional material; information sheets accompanying purchased product; websites and social media pages owned, created by, controlled by, or related to Defendants including, but not limited to, www.n-ergetics.com and www.essentialoilsessentialoils.com; and any other media over which Defendants have control, to determine whether the requirements of this Order have been met and whether Defendants are operating in conformity with this Order, the Act, and its implementing regulations;

D. Defendants have reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with Paragraph 8, at the rates set forth in Paragraph 16; and

E. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraph 8.A-B and 8.D of this Order. In no circumstance shall FDA's silence be construed as a substitute for written notification.

9. Within fifteen (15) business days after completing the recall of Defendants' colloidal silver products as described in Paragraph 8.B, Defendants shall give notice to FDA that, under FDA's supervision (which may be done by email or other means as FDA determines to be appropriate), Defendants are prepared to destroy all their colloidal silver products, including components and raw and in-process materials and finished product, in Defendants' possession, custody, or control. Defendants' notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall not commence or permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction. Within fifteen (15) business days after receiving written authorization from FDA to commence destruction, Defendants shall, under FDA's supervision (which may be done by email or other means as FDA determines to be appropriate), complete the destruction in compliance

with the FDA-authorized Destruction Plan. Defendants shall not dispose of any of their colloidal silver products (including components and raw and in-process materials and finished product) in a manner contrary to the provisions of the Act, any other federal law, or the laws or any State or Territory, as defined in the Act, in which the colloidal silver products are disposed. Defendants shall bear the costs of destruction and FDA's supervision thereof at the rates set forth in Paragraph 16.

10. Upon entry of this Order, Defendants, and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 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 (as defined by 21 U.S.C. § 321(p)) that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval;

B. Violating 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 (as defined by 21 U.S.C. § 321(g)(1)) that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions for use;

C. Violating 21 U.S.C. § 331(k) by causing articles of drug to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) while such articles are held for sale after shipment of one or more of their components in interstate commerce; and

D. Failing to implement and continuously maintain the requirements of this Order, the Act, and its implementing regulations.

11. After complying with the requirements of Paragraph 8.A-B and 8.D and receiving the notification from FDA pursuant to Paragraph 8.E, Defendants shall retain, at their expense, an independent person or persons (the "Auditor") who is qualified by education, training, and experience to determine whether Defendants' labels, labeling, promotional material, and websites cause Defendants' products, including but not limited to colloidal silver, to be unapproved new drugs and misbranded drugs; whether Defendants are directly or indirectly responsible for receiving, manufacturing, preparing, packing, labeling, holding, or distributing unapproved new drugs and misbranded drugs, including but not limited to colloidal silver; and whether Defendants directly or indirectly do any acts that cause drugs to become misbranded while they are held for sale after shipment of one or more of their components in interstate commerce. The Auditor shall be without personal or financial ties (other than a consulting agreement between the parties) to any Defendant or any of Defendants' employees or families. Defendants shall notify FDA in writing of the identity of the Auditor within ten (10) business days of retaining such Auditor. Thereafter:

A. Defendants shall ensure that the Auditor shall inspect Defendants' product labels; labeling; promotional material; information sheets accompanying purchased product; websites and social media pages owned, created by, controlled by, or related to Defendants including, but not limited to, www.n-ergetics.com and www.essentialoilsessentialoils.com; and any other locations which Defendants now or in the future, directly or indirectly engage in labeling, holding, and/or distributing drugs, no less frequently than once every six (6) months for a period of no less than five (5) years (the "Audit Inspections"). The first Audit Inspection shall

occur no more than six (6) months after Defendants' receipt of FDA's written notification pursuant to Paragraph 8.E;

B. At the conclusion of each Audit Inspection, Defendants shall ensure that the Auditor prepares a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this Order, the Act, and its implementing regulations, and identifying any deviations from such requirements ("Audit Report Observations") and shall provide a list of all materials reviewed, including all websites and social media, as well as copies of all such materials.

C. Defendants shall ensure that each Audit Report contains a written certification that the Auditor has personally reviewed all of Defendants' product labels; labeling; promotional material; information sheets accompanying purchased product; websites and social media pages owned, created by, controlled by, or related to Defendants including, but not limited to, www.n-ergetics.com and www.essentialoilsessentialoils.com; and any other locations at which Defendants, now or in the future, directly or indirectly engage in labeling, holding, and/or distributing drugs, and personally certifies (1) whether they contain claims that cause any of Defendants' products, including but not limited to their colloidal silver products, to be drugs within the meaning of the Act and, if so, whether those drugs are unapproved new drugs within the meaning of the Act; (2) whether Defendants are directly or indirectly receiving, manufacturing, preparing, packing, labeling, holding, or distributing colloidal silver products or other products that are misbranded within the meaning of the Act; and (3) whether Defendants are directly or indirectly doing any acts that cause drugs to become misbranded while they are held for sale after shipment of one of their components in interstate commerce.

D. Defendants shall ensure that the Audit Reports are delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date the Audit Inspection is completed. Additionally, Defendants shall maintain the Audit Reports in separate files at Defendants' Facility and shall promptly make the Audit Reports available to FDA upon request; and

E. If an Audit Report contains any Audit Report Observations indicating that Defendants' products are not in compliance with this Order, the Act, or its implementing regulations, Defendants shall immediately cease such activity.

12. If, at any time after this Order has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, product labels, labeling, websites, or social media pages owned or controlled by Defendants, a report prepared by Defendants' Auditor, or any other information, that Defendants have failed to comply with any provision of this Order, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Order, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of their noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any or all drugs;

B. Recall, at Defendants' expense, any drug that is an unapproved new drug, misbranded, or otherwise in violation of this Order, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Order;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Order, the Act, or its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 16.

13. Upon receipt of any order issued by FDA pursuant to Paragraph 12, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 12 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the Act, and its implementing regulations, and that Defendants may resume operations.

14. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' Facility and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order, the Act, and its implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to buildings, including but not limited to 303 W. 12th Street, Atoka, Oklahoma, 74525 and 339 W. 12th Street, Atoka, Oklahoma, 74525, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other promotional material therein; take photographs and make video recordings; take

samples of Defendants' in-process materials, unfinished and finished products, containers, packaging material, labeling, and other promotional material; and examine and copy all records relating to the receiving, manufacturing, preparing, packing, labeling, holding, or distributing of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate and apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

15. Defendants shall promptly, and no later than ten (10) business days after any FDA request, provide any information or records to FDA regarding Defendants' labels, labeling, promotional materials, websites or social media pages, and any other media over which Defendants have control, containing representations about the intended use(s) of Defendants' products; as well as the receipt, manufacture, preparing, packing, repacking, labeling, holding, and distribution of Defendants' products, including components.

16. Defendants shall reimburse FDA for the costs of supervision, inspection, investigation, review, examination, and analyses conducted pursuant to this Order or that FDA deems necessary to evaluate Defendants' compliance with this Order at the standard rates prevailing at the time the activities are accomplished. As of the date this Order is entered, these rates are: $101.00 per hour and fraction thereof per representative for inspection and supervision work; $121.06 per hour and fraction thereof per representative for laboratory and analytical work; $0.575 per mile plus tolls for travel expenses for travel by automobile; the government rate or equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these

rates shall be increased or decreased without further order of the Court. Defendants shall pay any such costs within ten (10) business days after being presented with an invoice for such costs from FDA.

17. Within five (5) business days after the entry of this Order, Defendants shall post a copy of this Order (a) on the homepage of their websites, www.n-ergetics.com and www.essentialoilsessentialoils.com, and on the homepage of any other website at which Defendants conduct business and (b) in a common area at Defendants' Facility and at any other location at which Defendants conduct business and shall ensure that the Order remains posted for as long as the Order remains in effect. Within ten (10) business days after entry of this Order, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, including but not limited to the identification of the websites on which the Order was posted.

18. Defendants shall notify FDA in writing, at least ten (10) business days before the creation of a new website (or link or reference, direct or indirect, to another website or other source) that conveys information about Defendants' colloidal silver products or any other of Defendants' drugs ("new website"). Defendants shall post a copy of this Order on any new website on the first day it is accessible to consumers. Within ten (10) business days after the creation of any new website, Defendants shall provide to FDA an affidavit, from a person with knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

19. Within ten (10) business days after the entry of this Order, Defendants shall hold a general meeting or series of smaller meetings (to include telephone or video calls) for all employees at which they shall describe the terms and obligations of this Order. Within fifteen

(15) business days after the entry of this Order, Defendants shall provide to FDA an affidavit, from a person with knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

20. Within ten (10) business days after the entry of this Order, Defendants shall provide a copy of the Order by personal service, certified mail (restricted delivery, return receipt requested), or email (delivery and read receipt requested) to each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them (collectively, "Associated Person(s)"). Within twenty (20) business days after the date of entry of this Order, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Order.

21. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Order, Defendants shall, within ten (10) business days after the commencement of such association, provide a copy of this Order, by personal service, certified mail (restricted delivery, return receipt requested), or email (delivery and read receipt requested) to such Associated Person(s), and provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Order pursuant to this paragraph.

22. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business that occurs after entry of this

Order, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of the company, or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Order. Defendants shall provide a copy of this Order to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

23. All notifications, correspondence, and communications to FDA required by the terms of this Order shall be prominently marked "Permanent Injunction Correspondence" and reference this civil action by case name and civil action number, and shall be sent by electronic mail to ORAPHARM2_RESPONSES@fda.hhs.gov and/or hard copy to Director, Compliance Branch, Office of Pharmaceutical Quality Operations, Division II, Office of Regulatory Affairs, Food and Drug Administration, 4040 North Central Expressway, Suite 300, Mail Code HFR-SW100, Dallas, Texas 75204.

24. All deadlines in this Order may be extended or shortened by mutual consent of FDA and Defendants in writing, without leave of Court.

25. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

26. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Order shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in

5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order 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.

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

DONE AND ORDERED in chambers in Muskogee, Oklahoma, this 29th day of October, 2020.

RONALD A. WHITE
UNITED STATES DISTRICT JUDGE