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

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

TEMPORARY RESTRAINING ORDER

1. Plaintiff has filed a Complaint for Injunction against Xephyr LLC doing business as N-Ergetics ("Xephyr"), a corporation based in the state of Oklahoma, and Brad Brand, Derill J. Fussell, and Linda Fussell, individuals (collectively, "Defendants"), pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, alleging that Defendants directly or indirectly do or cause the following acts:

A. Violate 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce new drugs, as defined in 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval;

B. Violate 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce drugs, as defined in 21 U.S.C. § 321(g), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

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

2. This Court has jurisdiction over the subject matter and Defendants.

3. The Complaint for Preliminary and Permanent Injunction alleges a cause of action against Defendants under the FDCA.

4. The United States has demonstrated that Defendants are violating the FDCA, 21 U.S.C. § 301, *et seq*. and that there is a cognizable danger that Defendants will continue to do so in the future unless a temporary restraining order is issued.

5. Because the United States' motion is based upon 21 U.S.C. § 332(a), which expressly authorizes injunctive relief to protect the public interest, no specific finding of irreparable harm is necessary, no showing of any inadequacy of other remedies at law is necessary, and no balancing of interests of the parties is required prior to the issuance of a temporary restraining order in this case.

6. Defendants have received advance notice.

7. The conditions for granting a temporary restraining order under Rule 65(b) of the Federal Rules of Civil Procedure and 21 U.S.C. § 332(a) having thus been met.

After considering the foregoing, it is therefore,

ORDERED, ADJUDGED, AND DECREED that the motion is **GRANTED**, in part:

1. The United States' Motion for a Temporary Restraining Order is **GRANTED** with notice to Defendants. This Temporary Restraining Order shall expire on **June 4, 2020**, **at**

12:00 p.m. unless it is extended by the Court for good cause shown or the Defendants consent to a longer extension.

2. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (hereinafter, "Associated Persons") who receive actual notice of this Order, shall not, during the pendency of this action, directly or indirectly, label, hold, and/or distribute any drug, including but not limited to colloidal silver, that does not have an approved new drug application pursuant to 21 U.S.C. § 355(b) or abbreviated new drug application pursuant to 21 U.S.C. § 355(j), or an investigational new drug application in effect for its use pursuant to 21 U.S.C. § 355(i), or any drug that is misbranded within the meaning of 21 U.S.C. § 352.

3. Upon entry of this Order, Defendants and Associated Persons, shall not, directly or indirectly, violate 21 U.S.C. § 331(k) by causing any drug, including but not limited to colloidal silver, to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) after shipment of one or more of its components in interstate commerce.

4. Upon entry of this Order, Defendants and Associated Persons shall immediately refrain from disposing of or transferring any assets that may interfere with implementation of payment of restitution to consumers who purchased Defendants' drugs, should the Court ultimately order such restitution payments in its final judgment in this matter.

5. Upon entry of this Order, Defendants and Associated Persons are prohibited from destroying, discarding, altering, transferring or otherwise making unavailable any

document or record in electronic format or otherwise within their custody or control that are related to (a) colloidal silver; (b) misbranded drugs; and/or (c) unapproved new drugs.

6. Representatives of FDA may be permitted, with prior court approval, to inspect Defendants' places of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. 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 (the "Facilities"), 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 or unfinished and finished products, containers, packaging material, labeling, and other promotional material; and examine and copy all records relating to the labeling, holding, and distribution of any and all drugs and their components.

7. The Defendants' reimbursement to the United States of America for the costs of supervision, inspection, investigation, review, examination, and analyses conducted pursuant to this Order is reserved for later determination.

8. Within eight (8) calendar days from entry of this Order, Defendants shall submit to FDA for its review and approval a recall strategy for Defendants' colloidal silver products. The recall strategy shall be submitted to FDA's ORA/OPQO Pharm II Recall Coordinator at orapharm2recalls@fda.hhs.gov and shall include customer notifications, public warning, methods for conducting effectiveness checks, and plans for the disposition of recalled products. Implementation of the recall plan will follow pending the Court's preliminary

injunction order, if entered, and FDA approval of a recall plan. Defendants shall bear the cost of the recall.

9. Defendants shall post a copy of this Order on (a) the homepage of their website, www.n-ergetics.com and on the homepage of any other website at which Defendants conduct business; and (b) in a common area at the Facilities and at any other location at which Defendants conduct business. Defendants shall ensure that the Order remains posted for as long as the Order remains in effect.

10. **IT IS FURTHER ORDERED** that the United States shall promptly provide notice of this action and this Order to Defendants by, to the extent necessary, attempting service at last known email addresses and physical addresses. Pursuant Rule 65(c) of the Federal Rules of Civil Procedure, Plaintiff United States of America shall not be required to post security for the instant action.

11. This matter is set for a preliminary injunction hearing on **May 21, 2020**, at **9:00 a.m.** in the United States District Courthouse, Muskogee, Oklahoma.

DONE AND ORDERED in chambers in Muskogee, Oklahoma, this 14th day of May, 2020.

Ronald A. White

RONALD A. WHITE
UNITED STATES DISTRICT JUDGE