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

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIV-** 20-140-RAW
	)	
XEPHYR LLC d/b/a N-ERGETICS, a corporation, and BRAD BRAND, DERILL J. FUSSELL, and LINDA FUSSELL, individuals,	)	
	)	
Defendants.	)	

UNITED STATES OF AMERICA'S COMPLAINT FOR PRELIMINARY AND PERMANENT INJUNCTION

Plaintiff, the United States of America, through its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), alleges that:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. § 332(a), to halt the sale of unproven and unapproved treatments for coronavirus, which includes coronavirus disease 2019 ("COVID-19") and any other disease. Specifically, Plaintiff seeks a permanent injunction to restrain and enjoin 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, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce unapproved new drugs;

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

C. Violating 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.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the parties and this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391.

CORPORATE AND INDIVIDUAL DEFENDANTS

4. Xephyr operates a website, www.n-ergetics.com, which offers colloidal silver products for sale in the United States and contains claims that colloidal silver is intended to cure, mitigate, treat, or prevent coronavirus, including COVID-19, and other diseases, including urinary tract infections, yeast infections, and pink eye. Xephyr also includes a print-out of information ("information sheets") about colloidal silver in packages of its purchased colloidal silver products that contain claims that colloidal silver is intended to cure, mitigate, treat, or prevent myriad other diseases, including cholera, cancer, diabetes, and AIDS. Xephyr is located at 303 W. 12th Street, Atoka, Oklahoma, 74525 and 339 W. 12th Street, Atoka, Oklahoma, 74525, and does business within the jurisdiction of this Court.

5. Brad Brand is an owner of Xephyr. Brad Brand is responsible for Xephyr's operations, including, but not limited to, labeling, holding, and/or distributing colloidal silver

products. Brad Brand performs his duties at 303 W. 12th Street, Atoka, Oklahoma, 74525 and 339 W. 12th Street, Atoka, Oklahoma, 74525.

6. Derill J. Fussell is an owner of Xephyr. Derill J. Fussell is responsible for Xephyr's operations, including, but not limited to, labeling, holding, and/or distributing colloidal silver products. Derill J. Fussell performs his duties at 303 W. 12th Street, Atoka, Oklahoma, 74525 and 339 W. 12th Street, Atoka, Oklahoma, 74525.

7. Linda Fussell is an owner of Xephyr. Linda Fussell is responsible for Xephyr's operations, including, but not limited to, labeling, holding, and/or distributing colloidal silver products. Linda Fussell performs her duties at 303 W. 12th Street, Atoka, Oklahoma, 74525 and 339 W. 12th Street, Atoka, Oklahoma, 74525.

DEFENDANTS UNLAWFULLY DISTRIBUTE UNAPPROVED NEW DRUGS

8. It is a violation of the Act to introduce or deliver for introduction into interstate commerce a "new drug" that is neither approved by FDA nor exempt from approval. 21 U.S.C. §§ 331(d) and 355(a). Specifically, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval pursuant to an effective investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j).

Defendants' Colloidal Silver Products Are Drugs

9. Under the FDCA, the definition of "drug" includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1)(B).

10. The intended use of a product may be determined from any relevant source, including labeling. *See* 21 C.F.R. § 201.128.

11. The Act defines "label" as, among other things, "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). The Act defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The labeling includes anything that explains the uses of the drug, whether or not it is physically attached to the product itself. *See Kordel v. United States*, 335 U.S. 350 (1948).

12. Defendants' colloidal silver products are drugs within the meaning of the Act because they are intended for use in the cure, mitigation, treatment, or prevention of disease in man. According to the labeling for Defendants' products, including but not limited to materials and links on Defendants' website and information accompanying purchased colloidal silver products, Defendants' colloidal silver products are intended to cure, mitigate, treat, or prevent coronavirus, which includes COVID-19, among other diseases.

13. Defendants' website contains claims that colloidal silver cures, mitigates, or treats coronavirus and other diseases. For example, the website states:

- Under the heading "Human Coronavirus":
    - "Influenzas, the flu, Wuhan China 2019 Novel (never seen before) Coronavirus Asian flu, bird flu, swine flu, Spanish flu, Cholera, bubonic plague and smallpox, are non-pharmaceutical intervention viruses . . . . The reason for non-pharmaceutical intervention, is that we have no known man-made drugs to control or kill virus. . . . However there was once an effective patented medicine, (now an over-the-counter supplement) that was used to treat pathogens for 123 years, ? (claims are ancedotal [sic])."

      The underlined "?" portion links to Defendants' Colloidal Silver page.

    - "Animal coronaviruses can rarely infect people and then spread between people as human to human infection, such as with MERS, SARS, but now we add the Wuhan 2019-nCOV virus to the formidable list. ? (staements [sic] are ancedotal [sic]) is still the only known anti-viral supplement to kill any of these viruses."

The underlined "?" portion links to Defendants' Colloidal Silver page.

- Under the heading "Pneumonia":
  - "The newest viral fear was called Coronavirus, but we still have avian influenza viruses (bird flu), (SARS), Middle East Respiratory Syndrome (MERS) virus, Legionella pneumonia, to battle with only one known remedy. The 127 year old mineral solution is ___?___ (claims are ancedotal [sic])"

    The underlined "?" portion links to Defendants' Colloidal Silver page.

- Under the heading "Colloidal Silver Pink Eye":

  - "Although the highly contagious eye infection called conjunctivitis or pink eye can be caused by bacteria or virus, there is one mineral remedy that is highly effective. ___?_____, a soothing effective home remedy for the contagious eye infection, pink eye."

    The underlined "?" portion links to Defendants' Colloidal Silver page.

14. Defendants' information sheets contain claims that colloidal silver cures, mitigates, or treats other diseases. For example, the information sheets state:

- Under the heading "What Experts Have Said About Colloidal Silver":

  - "Even cancer and AIDS patients are claiming alleged benefits from colloidal silver."

15. COVID-19 is a disease caused by a novel coronavirus dubbed "severe adult respiratory syndrome coronavirus 2" ("SARS-CoV-2"), which was first detected in December 2019. Reported illnesses for confirmed COVID-19 cases have ranged from mild to severe, with many thousands resulting in death. The Centers for Disease Control and Prevention has stated that the COVID-19 pandemic "poses a serious public health risk." https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html (last visited April 27, 2020).

16. Moreover, as the World Health Organization has explained, "there is no vaccine and no specific antiviral medicines against COVID-19." World Health Organization, *Q&A on*

Coronaviruses (COVID-19), (last visited Apr. 30, 2020), https://www.who.int/news-room/q-a-detail/q-a-coronaviruses; *see also* U.S. Centers for Disease Control and Prevention, *Therapeutic Options for COVID-19 Patients* (last visited Apr. 13, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html ("There are no drugs or other therapeutics approved by [FDA] to prevent or treat COVID-19. Current clinical management includes infection prevention and control measures and supportive care . . . .") (last visited May 8, 2020).

17. On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency, under 42 U.S.C. § 247d, for the entire United States in response to SARS-CoV-2.

18. On March 11, 2020, the World Health Organization announced that the COVID-19 outbreak was properly characterized as a worldwide pandemic.

19. On March 13, 2020, the President of the United States exercised his authority under the National Emergencies Act (50 U.S.C. § 1601 *et seq.*) and officially declared that the COVID-19 outbreak in the United States constituted a national emergency.

Defendants' Products Are New Drugs

20. Under the Act, a "new drug" is "[a]ny drug . . . the composition of which is such that" (1) "such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . ." or (2) "such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p)(1) and (2).

21. A new drug must satisfy three conditions to be "generally recognized as safe and effective" ("GRASE") within the meaning of 21 U.S.C. § 321(p)(1). First, there must be substantial evidence of its effectiveness. The Act defines "substantial evidence" as "evidence consisting of adequate and well-controlled investigations, including clinical investigations . . . on the basis of which it could fairly and responsibly be concluded by . . . [qualified] experts that the drug will have the effect it purports or is represented to have . . . " 21 U.S.C. § 355(d). Second, the investigations must be published in the scientific literature so that they are made generally available to the community of qualified experts and thereby subject to peer evaluation, criticism, and review. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652 (1973). Third, there must be a consensus among the experts, based on those published investigations, that the product is safe and effective under the conditions prescribed, recommended, or suggested in its labeling. *Id.*

22. FDA conducted comprehensive searches of the publicly-available medical and scientific literature for colloidal silver and determined that there are no published, adequate and well-controlled studies demonstrating that Defendants' colloidal silver products are safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Because there are no published adequate and well-controlled studies for the intended uses of Defendants' colloidal silver products to cure, mitigate, treat, or prevent coronavirus or any other disease, qualified experts have not come to the consensus of opinion that the products are effective for such uses. Therefore, Defendants' colloidal silver products are not GRASE and are new drugs under 21 U.S.C. § 321(p)(1).

Defendants' Colloidal Silver Products Are Unapproved New Drugs

23. After searching its records for NDA, ANDA, and IND submissions by Defendants, FDA determined that there are no approved NDAs or ANDAs and no INDs in effect for Defendants' colloidal silver products.

24. Therefore, Defendants' colloidal silver products are unapproved new drugs within the meaning of 21 U.S.C. § 355(a).

Defendants Distribute Unapproved New Drugs in Interstate Commerce

25. "Interstate commerce," under 21 U.S.C. § 321(b)(1), means commerce between any state and any place outside of it. On or about March 17, 2020, Defendants shipped colloidal silver from Oklahoma to Virginia, which constitutes distribution in "interstate commerce" within the meaning of 21 U.S.C. § 321(b)(1).

26. Therefore, Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, unapproved new drugs.

DEFENDANTS UNLAWFULLY DISTRIBUTE MISBRANDED DRUGS

27. Under the Act, a drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and it is not exempt from this requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

28. A prescription drug is "[a] drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by

law to administer such drug." 21 U.S.C. § 353(b)(1)(A). By law, adequate directions for lay use cannot be written for prescription drugs.

29. Defendants' colloidal silver products are prescription drugs because they are intended for curing, mitigating, treating, or preventing coronavirus, which includes COVID-19, as well as other diseases such as cholera, diabetes, cancer, and AIDS – all of which require diagnosis and management by a physician. Consequently, there are no adequate directions under which a layman can safely use this drug, because it is not safe for use except under the supervision of a physician.

30. Because Defendants' drug labeling does not bear adequate directions for use, their colloidal silver products are misbranded under 21 U.S.C. § 352(f)(1), unless they qualify for an exemption.

31. FDA has promulgated regulations establishing exemptions from the adequate directions for use requirement in 21 U.S.C. § 352(f)(1), but each exemption requires the drug to bear the labeling approved by FDA in an NDA. 21 C.F.R. §§ 201.100, 201.115. Because colloidal silver is not the subject of an approved NDA or ANDA, Defendants' colloidal silver products do not qualify for any exemption from the requirement that their labeling bear adequate directions for use. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115. Accordingly, Defendants' colloidal silver products are misbranded drugs.

Defendants Distribute Their Misbranded Drugs in Interstate Commerce

32. On or about March 17, 2020, Defendants shipped colloidal silver from Oklahoma to Virginia, which constitutes a distribution in interstate commerce within the meaning of 21 U.S.C. § 321(b)(1).

33. Defendants violate 21 US.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

DEFENDANTS CAUSE MISBRANDING OF DRUGS WHILE HELD FOR SALE, COMPONENTS OF WHICH DRUGS DEFENDANTS OBTAIN THROUGH INTERSTATE COMMERCE

34. Under 21 U.S.C. § 379a, "[i]n any action to enforce the requirements of this Act respecting a . . . drug . . . the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist." Upon information and belief, Defendants receive colloidal silver components or the finished colloidal silver products from outside of Oklahoma.

35. By labeling their colloidal silver products with claims that they cure, mitigate, treat, or prevent coronavirus (which includes COVID-19) and a litany of other serious diseases, Defendants cause their colloidal silver products to become misbranded drugs 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, in violation of 21 U.S.C. § 331(k).

FDA WARNED DEFENDANTS THAT THEIR CONDUCT IS UNLAWFUL

36. On March 6, 2020, FDA issued a Warning Letter (the "Warning Letter") to Defendants, warning them that they are violating the Act by distributing unapproved new drugs and misbranded drugs in interstate commerce. The Warning Letter also stated that "[t]he violations cited in this letter are not meant to be an all-inclusive list" and reminded Defendants that it was "[their] responsibility to ensure that the products [they] sell are in compliance with the FD&C Act and FDA's implementing regulations." The Warning Letter requested that Defendants respond within 48 hours by e-mail and describe the specific steps they have taken to correct the violations described in the letter. FDA further warned Defendants that failure to immediately correct their

violative conduct may result in legal action, including an injunction. The Warning Letter also stated: "If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. If you believe that your products are not in violation of the [FDCA], include your reasoning and any supporting information for our consideration."

37. Defendants posted FDA's Warning Letter to their website and also posted a "news release" that stated, among other things, "[o]ur website has addressed all issues pointed out in the letter." The "news release" further stated "[w]e sell several products including colloidal silver, an ex-prescription since 1938. This now, over the counter supplement has been laboratory, university and doctor tested to kill 650 pathogens in vitro." Thereafter, Defendants' temporarily took down the webpages that were referenced in the Warning Letter. As of April 22, 2020, however, claims related to the prevention and/or treatment of coronavirus with Defendants' colloidal silver products were present on Defendants' website.

38. Given Defendants' history and current actions, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Issue a preliminary and permanent injunction restraining and enjoining Xephyr LLC doing business as N-Ergetics, Brad Brand, Derill J. Fussell, and Linda Fussell, and each and all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and all persons in active concert or participation with any of them ("Associated Persons"), pursuant to 21 U.S.C. § 332(a) and the inherent equitable powers of the Court, from directly or indirectly doing or causing the following acts:

A. Violating 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. Violating 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. Violating 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.

II. Order that, pursuant to 21 U.S.C. § 374(a), FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished;

III. Order that Defendants make restitution to all purchasers of Defendants' colloidal silver products of the full amount paid by the purchaser, and that Defendants and Associated Persons immediately refrain from disposing of or transferring any assets that may interfere with implementation of such restitution payments;

IV. Order that, at Defendants' expense, Defendants recall their unapproved new drugs and misbranded drugs, pursuant to a plan approved by FDA;

V. Order that Defendants and Associated Persons be immediately prohibited from destroying, discarding, altering, transferring, or otherwise making unavailable any documents,

data, or records related to colloidal silver and their colloidal silver products, within the custody or control of Defendants and Associated Persons.

VI. Order that Plaintiff be awarded costs and such other equitable relief as the Court deems just and proper.

Respectfully submitted,

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