JEFFREY BOSSERT CLARK
Acting Assistant Attorney General
U.S. Department of Justice
CRAIG CARPENITO
United States Attorney
GUSTAV W. EYLER
Director
Consumer Protection Branch
DAVID E. DAUENHEIMER
Assistant United States Attorney
BRIANNA M. GARDNER
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, D.C. 20044
Tel: 202-532-4786
Brianna.M.Gardner@usdoj.gov

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. NATURAL SOLUTIONS FOUNDATION, an organization, and RIMA LAIBOW, and RALPH FUCETOLA, individuals, Defendants.	Civil Action No. 20-16016 **COMPLAINT FOR 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:

INTRODUCTION

1. The United States brings this suit under the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 332(a), to enjoin the sale of an unproven and unapproved treatment for coronavirus disease 2019 (COVID-19) and any other disease. Defendants market "Dr. Rima Recommends Nano Silver 10PPM," a purported "nano silver" product, which they have distributed as a cure or prevention for viral outbreaks, including the Ebola epidemic in the mid-2010s and, most recently, the ongoing COVID-19 pandemic. During the COVID-19 pandemic – despite being warned by FDA and the Federal Trade Commission (FTC) in the summer of 2020 that their conduct was unlawful – Defendants distributed their nano silver product accompanied, for example, by the claim that someone who takes "1 cap full . . . a day" of their product should have "no fear or concern" about coronavirus. When the U.S. Government notified Defendants of its intention to bring this lawsuit, Defendants put their nano silver product "On Hold" and removed some COVID-19-related claims from their public-facing websites, but made clear that their actions were a temporary stopgap and that they intended to challenge the government's position. Defendants' historical willingness to flout the law in the face of government warnings, and their continued assertion that their product is just "On Hold" and that their activity is lawful demonstrate the necessity of a permanent injunction to protect the public health in the midst of the ongoing pandemic.

2. Specifically, Plaintiff seeks an order to restrain and enjoin Natural Solutions Foundation (NSF), an organization with its principal place of business in New Jersey, and Dr. Rima Laibow and Ralph Fucetola, individuals, from:

A. Violating 21 U.S.C. § 331(d), by introducing or causing to be introduced, or delivering for introduction or causing to be delivered for introduction, into interstate

commerce a new drug, as defined in 21 U.S.C. § 321(p), that is neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval; and

B. Violating 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering for introduction or causing to be delivered for introduction, into interstate commerce a drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1).

JURISDICTION

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

4. This Court has personal jurisdiction over the parties. NSF is a formerly registered non-profit organization based in New Jersey. Upon information and belief, it is now an unincorporated association based in New Jersey. NSF's principal place of business is 58 Plotts Road, Newton, NJ 07860. Ralph Fucetola performs his duties at NSF's principal place of business in New Jersey. Dr. Rima Laibow has sufficient minimum contacts with New Jersey through her actions on behalf of NSF such that the Court has jurisdiction over her.

DEFENDANTS

5. Until just weeks ago, NSF publicly sold and distributed a product known as "Dr. Rima Recommends Nano Silver 10PPM" (nano silver product). NSF operates various websites, including: www.nsfmarketplace.com; www.drrimatruthreports.com; www.inhere.org; www.opensourcetruth.com; and www.truthaboutcoronavirus.com. Two of the websites, www.nsfmarketplace.com and www.inhere.org, offered Defendants' nano silver product for sale. The other websites, www.drrimatruthreports.com and www.opensourcetruth.com, contain links to www.nsfmarketplace.com, and www.truthaboutcoronavirus.com re-directs to

www.opensourcetruth.com. NSF's website, www.opensourcetruth.com, contained claims that Defendants' nano silver product is intended to cure, mitigate, treat, or prevent COVID-19.

6. Upon information and belief, NSF is an unincorporated association based in New Jersey. NSF's principal place of business is 58 Plotts Road, Newton, New Jersey 07860, and it does business within the jurisdiction of this Court.

7. Dr. Rima Laibow is the medical director for NSF, as well as the face and namesake of Defendants' nano silver product. Dr. Laibow shares responsibility with Ralph Fucetola for the operations of NSF, within the jurisdiction of this Court, including, but not limited to, labeling, holding, and/or distributing Defendants' nano silver product.

8. Ralph Fucetola is the vice president of legal affairs, as well as a trustee and attorney, for NSF. Ralph Fucetola shares responsibility with Dr. Laibow for NSF's operations, including, but not limited to, labeling, holding, and/or distributing Defendants' nano silver product. Ralph Fucetola performs his duties at 58 Plotts Road, Newton, New Jersey 07860.

VENUE

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

A PERMANENT INJUNCTION IS NECESSARY

10. Defendants unlawfully distributed their nano silver product in interstate commerce in violation of the Act despite multiple warnings from FDA. Defendants only attempt to conform with the law when faced with the prospect of government enforcement. As demonstrated by Defendants' pattern of behavior since 2014, along with their assertions that their product is just "On Hold" and that their activity is lawful, injunctive relief is necessary to permanently enjoin Defendants from violating the Act by distributing unapproved new drugs

(that is, products intended to cure, mitigate, treat, or prevent disease that do not have FDA approval for those uses) and by distributing such drugs without adequate directions for use.

DEFENDANTS UNLAWFULLY DISTRIBUTED AN UNAPPROVED NEW DRUG

11. It is a violation of the Act to introduce or cause to be introduced, or deliver for introduction or cause to be delivered 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 NDA (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' Nano Silver Product Is a Drug

12. Under the Act, 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).

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

14. The Act defines a "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). Labeling includes anything that explains the uses of a product, whether or not it is physically attached to the product itself. *See generally Kordel v. United States*, 335 U.S. 350 (1948).

15. Defendants' nano silver product is a drug within the meaning of the Act because it is intended for use in the cure, mitigation, treatment, or prevention of disease in man. According to the labeling for Defendants' product, including but not limited to Defendants' website www.opensourcetruth.com, Defendants' nano silver product can be used to cure, mitigate, treat, or prevent COVID-19.

16. For example, prior to the government contacting Defendants regarding this lawsuit, Defendants' website www.opensourcetruth.com contained claims that their nano silver product cures, mitigates, treats, or prevents COVID-19. Those claims included:

- Under the heading "COVID Second Wave," where the underlined "Nano Silver 10 PPM" links to https://nsfmarketplace.com/mainstore:
  > "Use Nano Silver 10 PPM, which has been shown, in vitro, to support normal cell membrane integrity – and it is your cell membrane that is your last line of defense against the COVID virus adhering, penetrating and replicating. No replication, no disease."

- Under the heading "OST Establishes Coronavirus News Aggregation Site":
  > "Speaking of potentially lethal, it does not matter if the novel coronavirus is a weaponized version of a natural virus or not in terms of infection. What matters is that your immune system prevents it from making you sick or spreading it to others. And the very best way I know to do that is to support your immune function with my evidence-based, non-toxic Nano Silver 10 PPM. I take 1 cap full prophylactically once a day and have absolutely no fear or concern about coming down with whatever this, or any other, bug can do. *None*. . . . And it is available at www.nsfmarketplace.com."

17. COVID-19 is a disease caused by a novel coronavirus called "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2), which was first detected in or around December 2019. Reported illnesses for confirmed COVID-19 cases have ranged from mild to severe, with over one million cases resulting in death around the world. The Centers for Disease Control and Prevention (CDC) has stated that the COVID-19 pandemic "is a serious global

health threat." CDC, *Global COVID-19*, https://www.cdc.gov/coronavirus/2019-ncov/global-covid-19/ (last visited October 22, 2020).

18. 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.

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

20. 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' Nano Silver Product Is a New Drug

21. Under the Act, a "new drug" is "[a]ny drug . . . the composition of which is such that 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 . . . ." 21 U.S.C. § 321(p)(1).

22. For a new drug to be "generally recognized as safe and effective" (GRASE) within the meaning of 21 U.S.C. § 321(p)(1), three conditions must be satisfied. 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.*

23. FDA conducted comprehensive searches of the publicly available medical and scientific literature for nano silver and determined that there are no published, adequate and well-controlled studies demonstrating that Defendants' nano silver product is safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. Because there are no published adequate and well-controlled studies for the intended use of Defendants' nano silver product to cure, mitigate, treat, or prevent COVID-19, qualified experts have not come to the consensus of opinion that the product is effective for such use. Therefore, Defendants' nano silver product is not GRASE and is a new drug under 21 U.S.C. § 321(p)(1).

Defendants' Nano Silver Product Is an Unapproved New Drug

24. 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' nano silver product.

25. Therefore, Defendants' nano silver product is an unapproved new drug within the meaning of 21 U.S.C. § 355(a).

Defendants Distribute an Unapproved New Drug in Interstate Commerce

26. "Interstate commerce," under 21 U.S.C. § 321(b)(1), means commerce between any state and any place outside of it. On or about July 24, 2020, Defendants shipped, or caused the shipment of, their nano silver product from Arizona to Maryland, which constitutes distribution in "interstate commerce" within the meaning of 21 U.S.C. § 321(b)(1).

27. Therefore, Defendants violate 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering for introduction or causing to be delivered for introduction, into interstate commerce an unapproved new drug.

DEFENDANTS UNLAWFULLY DISTRIBUTE A MISBRANDED DRUG

28. 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.

29. 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). As a matter of law, adequate directions for lay use cannot be written for prescription drugs.

30. Defendants' nano silver product is a prescription drug because it is intended for use in curing, mitigating, treating, or preventing COVID-19, a disease that requires 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.

31. Because Defendants' drug labeling does not bear adequate directions for use, their nano silver product is misbranded under 21 U.S.C. § 352(f)(1), unless it qualifies for an exemption.

32. FDA has promulgated regulations establishing exemptions from the adequate directions for use requirement in 21 U.S.C. § 352(f)(1), but Defendants' nano silver product does

not meet any of these exemptions because it is not the type of drug exempted (*see* 21 C.F.R. §§ 201.105 (veterinary drug), 201.116 (drugs having commonly known directions), 201.117 (inactive ingredients), 201.119 (in vitro diagnostic products), 201.120 (prescription chemicals or components), 201.122 (drugs for processing, repacking, or manufacturing), 201.125 (drugs for use in teaching, law enforcement, research, and analysis), 201.129 (radioactive drugs for research use)), and it is not the subject of an approved application or an effective IND (*see* 21 C.F.R. §§ 201.100(c)(2), 201.115). Accordingly, Defendants' nano silver product is a misbranded drug.

Defendants Distribute a Misbranded Drug in Interstate Commerce

33. On or about July 24, 2020, Defendants shipped, or caused the shipment of, their nano silver product from Arizona to Maryland, which constitutes a distribution in interstate commerce within the meaning of 21 U.S.C. § 321(b)(1).

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

FDA REPEATEDLY WARNED DEFENDANTS THAT THEIR CONDUCT IS UNLAWFUL, AND DEFENDANTS ONLY ALTERED THEIR BEHAVIOR AFTER THREAT OF GOVERNMENT ENFORCEMENT

35. On May 19, 2020, FDA and the FTC jointly issued a Warning Letter (2020 Warning Letter) to Defendants, informing them that they are violating the Act by distributing unapproved new drugs and misbranded drugs in interstate commerce. The 2020 Warning Letter cited examples of claims in Defendants' product labeling (three webpages on opensourcetruth.com) that establish that the intended use of their nano silver product is to treat or prevent COVID-19, making the product a drug under the Act. For example, the 2020 Warning

Letter noted that Defendants claimed: "Once you have access to The Silver Solution, Nano Silver 10 PPM, you have no reason to participate in the COVID-19 panic! . . . This Nano Silver 10 PPM is your totally non-toxic key to halting COVID-19 APR - Attachment, Penetration and Replication - to keep yourself and those you love healthy." The 2020 Warning Letter also noted that Defendants stated: "[S]cientific documentation, . . . shows that in the presence [of] my Nano Silver 10 PPM, available at http://www.NSFMarketplace[.]com, . . . the action of SARS, widely believed to be the parent virus of COVID19, is stopped dead in its tracks. . . . It is my considered opinion, based on the evidence and science available to me that this particular Nano Silver 10 PPM, plus sensible hand-washing … can be literally life-saving in pandemic situations." The 2020 Warning Letter also stated that the letter was "not meant to be an all-inclusive list of violations that exist in connection with [Defendants'] products or operations" and instructed 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 2020 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 informed Defendants that failure to immediately correct their violative conduct may result in legal action, including an injunction. The 2020 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 [Act], include your reasoning and any supporting information for our consideration."

36. Defendant Ralph Fucetola responded to the 2020 Warning Letter on August 11, 2020. In his response, he stated that NSF "has taken immediate steps to suspend public access to the three web pages specifically noted in the Letter which are now preserved as private pages on

the Open Source Truth website" but that "[i]t may take [NSF] up to a month to review all pages and make the changes suggested." Mr. Fucetola did not elaborate on who could view the "private pages on the Open Source Truth website." Mr. Fucetola's response further stated, "[w]e do not consider the language we used to be in any way improper" and that "in the context of the Declared Pandemic, we assert we have a First Amendment protected right to communicate about the importance of a well-functioning immune system and the benefits of nutrient support for optimal immune system function. To do that we have to mention COVID." As of September 14, 2020, the claims noted in Paragraph 16 of this Complaint remained publicly accessible on opensourcetruth.com.

37. The 2020 Warning Letter was not the first time FDA informed Defendants that they were violating the Act by illegally distributing unapproved new drugs. In 2014, FDA and FTC jointly issued a Warning Letter (2014 Warning Letter) listing numerous claims by Defendants that their nano silver product was intended to cure, mitigate, treat, or prevent Ebola. For example, at the time the government issued the 2014 Warning Letter, Defendants stated on their website www.drrimatruthreports.com: "[N]ano silver was known . . . as the definitive antiviral agent against Ebola virus[]." Then, during an inspection in 2018, an FDA investigator notified Defendant Ralph Fucetola that a review of the same website, www.drrimatruthreports.com, at that time revealed that Defendants were continuing to promote their nano silver product to cure, mitigate, treat, or prevent Ebola. As of September 29, 2020, Defendants were still making claims about their nano silver product and Ebola, publicly stating, on their website www.drrimatruthreports.com, among other things, "Ebola's Back? Must Have Nano Silver!"

38. On September 8, 2020, the United States informed Defendants of its intention to file this lawsuit and then instructed Defendants to remove the claims noted in Paragraph 16 of this Complaint. Defendants removed the claims from public view on or about September 16, 2020. However, as of October 13, 2020, Defendants' claims about their nano silver product and COVID-19 were still on their YouTube channel, "NaturalSolutions." For example, in the video entitled, "COVID-19 Emergency Health Summit: Dr. Rima Speaks," Dr. Laibow stated that it is "vitally important to get" Defendants' nano silver product, directed viewers to nsfmarketplace.com, and stated that nano silver 10 parts per million "controls the virus." And, as of October 21, 2020, Defendants state on www.nsfmarketplace.com that sale of their nano silver product is "Currently On Hold" but that "Rest Assured, our legal challenge is under way!"

39. Defendants' history of non-compliance coupled with their belated, incomplete responses to warnings regarding their illegal conduct, and assertions that their product is just "On Hold" and that their activity is lawful, demonstrate that they will continue to violate the Act in the manner set forth in this Complaint unless restrained by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Issue an order restraining and enjoining Natural Solutions Foundation, Dr. Rima Laibow, and Ralph Fucetola, 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 authority of the Court, from directly or indirectly:

A. Violating 21 U.S.C. § 331(d), by introducing or causing to be introduced, or delivering for introduction or causing to be delivered 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; and

B. Violating 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering for introduction or causing to be delivered 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).

II. Order that, along with FDA's authority 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, at Defendants' expense, Defendants recall their unapproved new drugs and misbranded drugs pursuant to a plan approved by FDA;

IV. 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 their nano silver product, misbranded drugs, and/or unapproved new drugs, within the custody or control of Defendants and Associated Persons;

V. Order that Defendants be required to pay restitution in an amount to be determined; and

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

Date: November 13, 2020

Respectfully submitted,

JEFFREY BOSSERT CLARK
Acting Assistant Attorney General
U.S. Department of Justice

GUSTAV W. EYLER
Director
Consumer Protection Branch

CRAIG CARPENITO
United States Attorney

DAVID E. DAUENHEIMER
Assistant United States Attorney
U.S. Attorney's Office
District of New Jersey

/s/ Brianna M. Gardner
BRIANNA M. GARDNER
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, D.C. 20044
202-532-4786
Brianna.M.Gardner@usdoj.gov
Counsel for the United States of America

OF COUNSEL:

ROBERT P. CHARROW
General Counsel
U.S. Department of Health and Human Services

STACY CLINE AMIN
Chief Counsel
U.S. Food and Drug Administration
Deputy General Counsel
U.S. Department of Health and Human Services

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation
U.S. Food and Drug Administration

JACLYN E. MARTÍNEZ RESLY
Associate Chief Counsel for Enforcement
U.S. Department of Health and Human Services
Office of the Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 32, Room 4397
Silver Spring, MD 20993

Phone: (301) 348-3932
Jaclyn.MartinezResly@fda.hhs.gov