

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA

Plaintiff,

v.

B4B EARTH TEA LLC, a limited liability
company;

B4B CORP., a corporation; and

ANDREW MARTIN SINCLAIR, individually
and as an officer of B4B EARTH TEA LLC and
B4B CORP.,

Defendants.

**COMPLAINT FOR CIVIL
PENALTIES, PERMANENT
INJUNCTION, MONETARY
RELIEF, AND OTHER RELIEF**

Civil Action No.: 22-CV-1159

Plaintiff, the United States of America, acting upon notification and authorization to the Attorney General by the Federal Trade Commission (“FTC”), pursuant to Section 16(a)(1) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 56(a)(1), and on behalf of the United States Food and Drug Administration (“FDA”), alleges:

NATURE OF THE CASE

1. The United States brings this action for permanent injunctive relief, civil penalties, and other remedies pursuant to the FTC Act, 15 U.S.C. § 45(a), § 45(m)(1)(A), § 52, and § 57a(a)(1)(B), the COVID-19 Consumer Protection Act, Pub. L. No. 116-260, Title XIV, § 1401(b)(1), and the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 331(d), against B4B Earth Tea LLC, B4B Corp., and Andrew Martin Sinclair (“Defendants”). The

Defendants manufacture and sell an herbal tea product called B4B Earth Tea Extra Strength (“Earth Tea”). Defendants sell Earth Tea for \$60 per 16-ounce bottle. Defendants have been advertising Earth Tea on social media and the internet as a product capable of preventing and treating the Coronavirus Disease 2019 (“COVID-19”), even claiming that it is more effective than the available COVID-19 vaccines. Defendants lack competent and reliable scientific bases for these claims, and their use of deceptive advertising and misinformation, exploiting fears in the midst of a pandemic to sell their product to concerned consumers, poses a significant risk to public health and safety.

2. The Federal Trade Commission (“FTC”) has repeatedly warned Defendants that their deceptive advertising and misrepresentations violate the FTC Act and the COVID-19 Consumer Protection Act. The U.S. Food and Drug Administration (“FDA”) has similarly warned Defendants that as currently marketed, Earth Tea is an unapproved new drug, and its sale into interstate commerce a violation of the FDCA, 21 U.S.C. § 331(d). Despite these warnings, Defendants continue to make deceptive and misleading statements about the ability of Earth Tea to prevent and treat COVID-19. The United States therefore brings this suit seeking permanent injunctive relief, civil penalties, and other remedies in order to prevent the harms caused by Defendants’ ongoing misrepresentations.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this action pursuant to (1) 28 U.S.C. § 1331, because it arises under the law of the United States; (2) 28 U.S.C. § 1337(a), because it arises under an Act of Congress regulating interstate commerce or protecting trade and commerce against restraints and monopolies; (3) 28 U.S.C. § 1345, because the United States is the Plaintiff; (4) 28 U.S.C. §1355, because the United States seeks a civil penalty; and

(5) 21 U.S.C. 332(a) for violations of Section 331 of the FDCA.

4. At all times relevant to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

5. The Court has personal jurisdiction over the defendants because the majority of Defendants reside in this district and because the alleged acts giving rise to the claims occurred in this District.

6. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c), and 15 U.S.C. § 53(b), because the majority of Defendants reside in this District and because a substantial part of the events or omissions giving rise to the claims occurred in this District.

PARTIES

7. Plaintiff is the United States of America.

8. Defendant B4B Earth Tea LLC is a New York limited liability company with its principal place of business at 40 Remsen Ave., Brooklyn, New York 11212. B4B Earth Tea LLC transacts or has transacted business in this District and throughout the United States. At all times relevant to this Complaint, acting alone or in concert with others, Defendant B4B Earth Tea LLC has manufactured, advertised, marketed, distributed, or sold Earth Tea, an herbal tea containing water, honey, aloe vera, and herbs, to consumers throughout the United States.

9. Defendant B4B Corp. is a Michigan corporation with the address of the incorporator listed at 19179 Ilene St., Detroit, Michigan 28221. On information and belief, B4B Corp. conducts business at 40 Remsen Ave., Brooklyn, New York 11212, and transacts or has transacted business in this District and throughout the United States. At all times relevant to this

Complaint, acting alone or in concert with others, B4B Corp. has manufactured, advertised, marketed, distributed, or sold Earth Tea, an herbal tea containing water, honey, aloe vera, and herbs, to consumers throughout the United States.

10. Defendant Andrew Martin Sinclair, who also calls himself “Busta Sinclair,” is the sole individual identified as founder, owner, agent, or principal officer of B4B Earth Tea LLC and B4B Corp. (jointly, “Corporate Defendants”). At all times relevant to this Complaint, acting alone or in concert with others, Defendant Sinclair has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of the Corporate Defendants, including the acts and practices set forth in this Complaint. Defendant Sinclair is actively involved in Corporate Defendants’ business affairs. He created and manufactures Earth Tea and participates in promotions for Earth Tea through, among other things, posts on Facebook, TikTok, Twitter, Instagram, and YouTube accounts; personal appearances in videos posted on TikTok, Twitter, and YouTube; broadcasts on Instagram; and email communications with consumers who order Earth Tea. He has made representations in these online videos and social media posts about the purported efficacy of Earth Tea to prevent, mitigate, treat, or cure COVID-19. He also responded directly to a February 18, 2021 joint warning letter from the FTC and FDA to B4B Corp. about false or unsubstantiated advertising claims about Earth Tea and to subsequent communications from FTC staff. Defendant Sinclair resides in this District and, in connection with the matters alleged herein, transacts or has transacted business in this District and throughout the United States.

THE FTC ACT

11. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits “unfair or deceptive acts

or practices in or affecting commerce.”

12. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

13. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Earth Tea is a “drug” as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

THE COVID-19 CONSUMER PROTECTION ACT

14. On January 31, 2020, the Secretary of Health and Human Services declared that COVID-19 had caused a public health emergency. As of the date of the filing of this complaint, the public health emergency remains in effect.

15. The COVID-19 Consumer Protection Act, signed into law on December 27, 2020, makes it unlawful, for the duration of the ongoing novel coronavirus (COVID-19) public health emergency, for any person, partnership, or corporation to engage in a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), that is associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19. COVID-19 Consumer Protection Act of the 2021 Consolidated Appropriations Act, Pub. L. No. 116-260, Title XIV, § 1401(b)(1).

16. A violation of Section (b)(1) of the COVID-19 Consumer Protection Act is treated as a violation of a rule defining an unfair or deceptive act or practice proscribed under section 18(a)(1)(B) of the FTC Act, 15 U.S.C. § 57a(a)(1)(B). COVID-19 Act, § 1401(c)(1).

17. A violation of Section (b)(1) of the COVID-19 Consumer Protection Act made with the knowledge required by Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. § 45(m)(1)(A), is subject to monetary civil penalties of not more than \$46,517 for each violation of the COVID-19 Consumer Protection Act after January 13, 2021, including penalties whose associated violation predated January 13, 2021. *See* 15 U.S.C. § 45(m)(1)(A), as modified by Section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114-74, sec. 701, 129 Stat. 599 (2015); *see also* 16 C.F.R. § 1.98(d).

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

18. A product is a drug within the meaning of the FDCA if, among other things, it is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.” 21 U.S.C. § 321(g)(1)(B).

19. The intended use of a product “refer[s] to the objective intent of the persons legally responsible for the labeling of drugs” and may be determined from any relevant source, including the circumstances surrounding the distribution of the article, product labeling, advertising, promotional material, or oral or written statements by such persons or their representatives. *See* 21 C.F.R. § 201.128.

20. The FDCA 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 term “accompanying” in the second clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at issue; physical attachment to the article is not necessary. *See Kordel v. United States*, 335 U.S. 345, 349-50 (1948). It is the

textual relationship and integrated nature of the transaction that is significant. *See id.* at 350.

21. A “new drug” is defined as any 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. . . . ; or any drug . . . the composition of which is such that 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).

22. The FDCA prohibits doing or causing the introduction or delivery for introduction into interstate commerce of any new drug 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 because, for example, it is the subject of an approved investigational new drug application (“IND”). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j). It is a violation of the Act to introduce or deliver, or cause to be introduced or delivered, into interstate commerce a new drug that is neither approved nor exempt from approval. 21 U.S.C. § 331(d).

DEFENDANTS’ UNLAWFUL CONDUCT

I. Defendants Deceptively Advertise Earth Tea as a Drug That Prevents or Treats COVID-19

23. Defendants are the sole manufacturers of Earth Tea. Defendants sell Earth Tea for \$60 per 16-ounce bottle, and consumers can purchase Earth Tea through the Corporate Defendants’ website, b4bearhteallc.com (formerly b4bcorp.com).

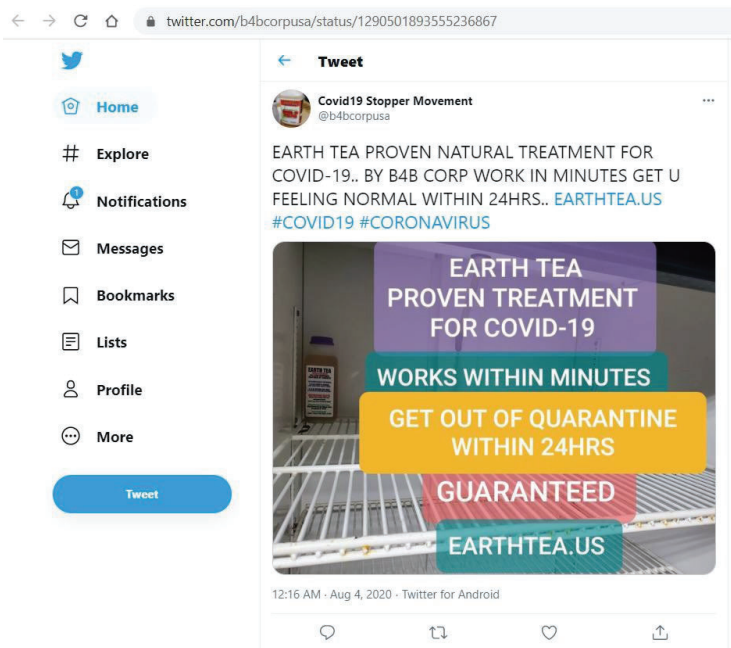
24. Since at least April 2020, Defendants have advertised Earth Tea to prevent, mitigate, treat, or cure COVID-19. Defendants advertise, label, or promote Earth Tea on the Internet, including on the website b4bearhteallc.com (formerly b4bcorp.com), and through social media posts and videos, including on Facebook, Instagram, Twitter, TikTok, and YouTube.

25. Through the websites b4bearhteallc.com and b4bcorp.com, and postings on TikTok, Twitter, Instagram, and YouTube, Defendants disseminated or caused to be disseminated advertisements for Earth Tea, including but not necessarily limited to the following statements and depictions.

A. Claims that Earth Tea Prevents or Treats COVID-19

26. Defendants have posted on social media multiple claims that Earth Tea prevents or treats COVID-19, as illustrated by the following screenshots:

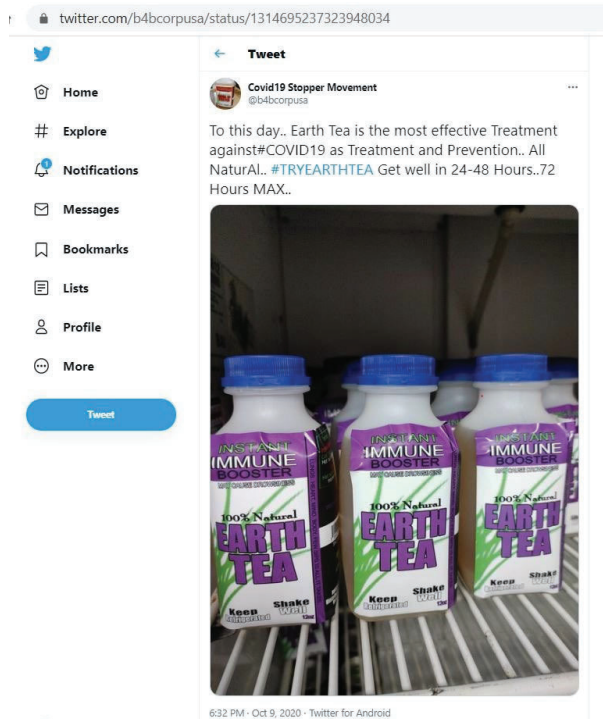
Twitter b4bcorpUSA Aug. 4, 2020 (captured 01.28.2021)



“Covid 19 Stopper Movement
EARTH TEA PROVEN
NATURAL TREATMENT FOR
COVID-19.. BY B4B CORP
WORK IN MINUTES GET U
FEELING NORMAL WITHIN
24HRS.. EARTHTEA.US
#COVID19 #CORONAVIRUS”

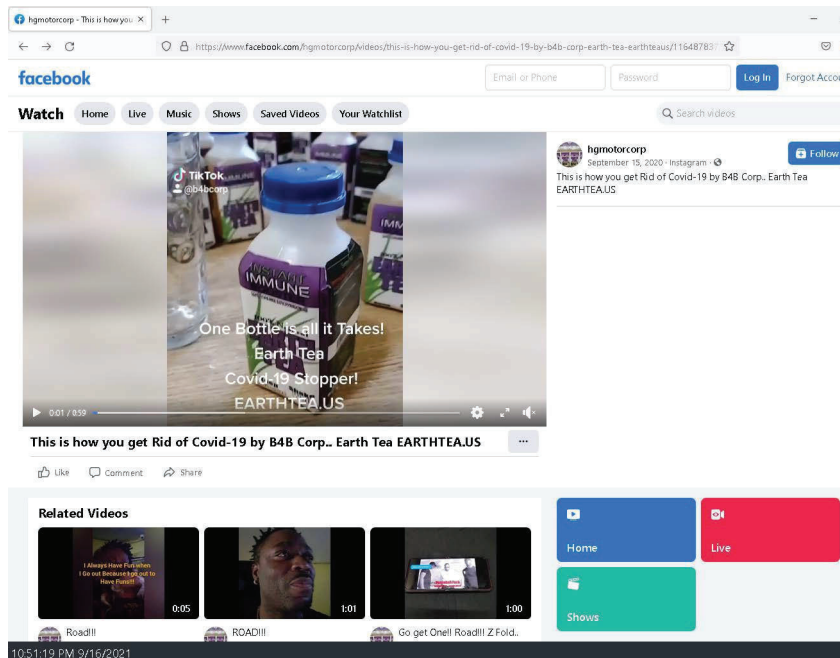
“EARTH TEA PROVEN
TREATMENT FOR COVID-19
WORKS WITHIN MINUTES
GET OUT OF QUARANTINE
WITHIN 24HRS
GUARANTEED
EARTHTEA.US”

Twitter b4bcorpora Oct. 9, 2020 (captured 1.28.21)



“Covid 19 Stopper Movement
To this day.. Earth Tea is the most effective Treatment against#COVID19 as Treatment and Prevention..All NaturAl..#TRYEARTHTEA Get well in 28-48 Hours..72 Hours MAX..”

Facebook HGmotorcorp with TikTok Video (captured 9.16.21)



[Embedded TikTok Video narrated by Defendant Sinclair demonstrating how to consume Earth Tea to “get rid of Covid-19.” Video superscript appears through duration of video “One Bottle is all it Takes! Earth Tea Covid-19 Stopper”]

YouTube Earthtea.US Feb. 8, 2021 (captured 10.18.21)



[Defendant Sinclair discusses how he was cured of Covid-19, and how 48 consumers who tried Earth Tea were cured.]

“[W]e’re up to 48 out of 48. That’s 48 people who called and said they have symptoms or they tested positive and they tried Earth Tea.... They get a bottle. Drink half cold and then half hot before they go to bed, wake up the next morning, the symptoms gone.”

“I understand the skepticism.... But I’ll say you don’t have to die, you don’t have to suffer.... You get this tea, you drink it, you go to sleep and wake up tomorrow...you’re good to go.”

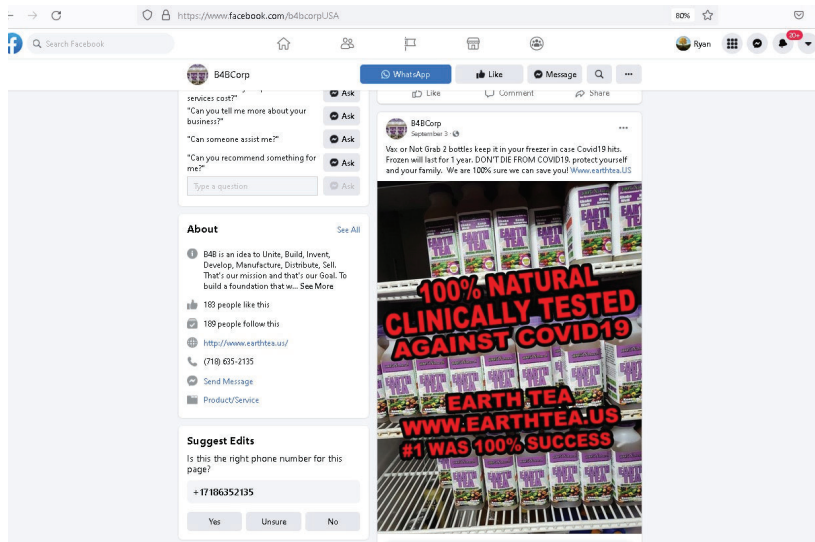
TikTok B4BEarthtea Aug. 28, 2021 (captured 10.13.21)



[Defendant Sinclair appears in and narrates “COVID19 CHALLENGE” demonstrating how to consume Earth Tea to get rid of Covid-19.]

“Pour half the bottle in a cup cold and then you drink the other half hot before you go to sleep, all right? Simple.... And then guess what? COVID-19, gone.”

Facebook b4bcorpUSA Sep. 3, 2021 (captured 10.20.21)



“Vax or Not Grab 2 bottles keep it in your freezer in case Covid19 hits. Frozen will last for 1 year. DON'T DIE FROM COVID19. Protect yourself and your family. We are 100% sure we can save you!”

B. Claims That Scientific Research Proves Earth Tea Prevents or Treats COVID-19

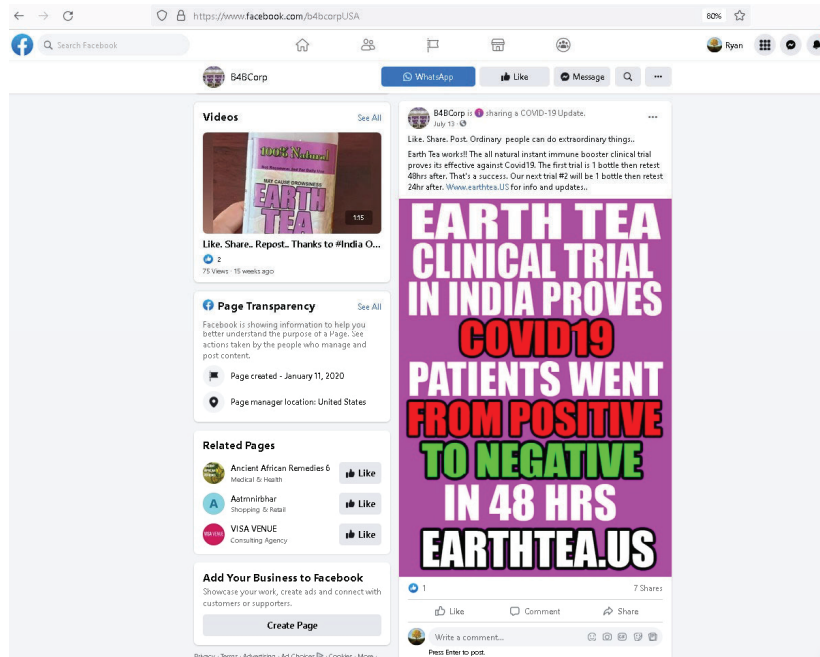
27. Defendants compound their misrepresentations that Earth Tea prevents or treats COVID-19, with unsubstantiated claims that there is competent and reliable scientific research that supports these misrepresentations. In fact, at present, there is no published report of any well-controlled human clinical study to substantiate that Earth Tea can treat, prevent, or cure COVID-19. Defendants purport to possess anecdotal evidence from customers, and they also rely on a 15-person purported study that Defendants state was conducted in India. Neither the purported anecdotal reports nor this small, unpublished study suffices as competent and reliable scientific evidence to substantiate the claimed health benefits.

28. The study, as described in a report on Defendants' b4bearhteallc.com website, purportedly consisted of a single group of 15 adults with “mild COVID-19” who were evaluated for symptoms, given two 8-ounce doses of Earth Tea and evaluated again four to five days later.

The report claims, without documentation or any supporting data analysis, that there was “statistically significant efficacy” of the product including “a significant result” in RT-PCR lab tests for the COVID-19 infection. The unpublished results of this study, even if accurately presented in the report on Defendants’ website, do not comprise competent and reliable scientific evidence of any benefit of Earth Tea relating to COVID-19. Among other reasons, there was no control group to establish that Earth Tea performed any better than a placebo. The anecdotal reports are not documented, and even if accurate, do not constitute competent and reliable human clinical evidence that consuming Earth Tea caused any improvement in COVID-19 symptoms.

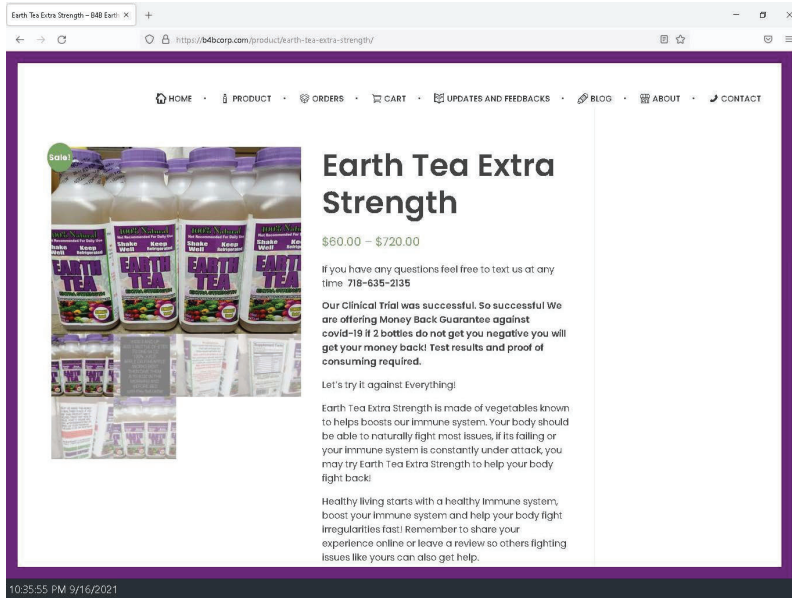
29. Notwithstanding this, Defendants disseminated or caused to be disseminated statements claiming that the clinical trial establishes that Earth Tea is effective at preventing or treating COVID-19, including the following:

Facebook b4bcorpUSA July 13, 2021 (captured 10.20.21)

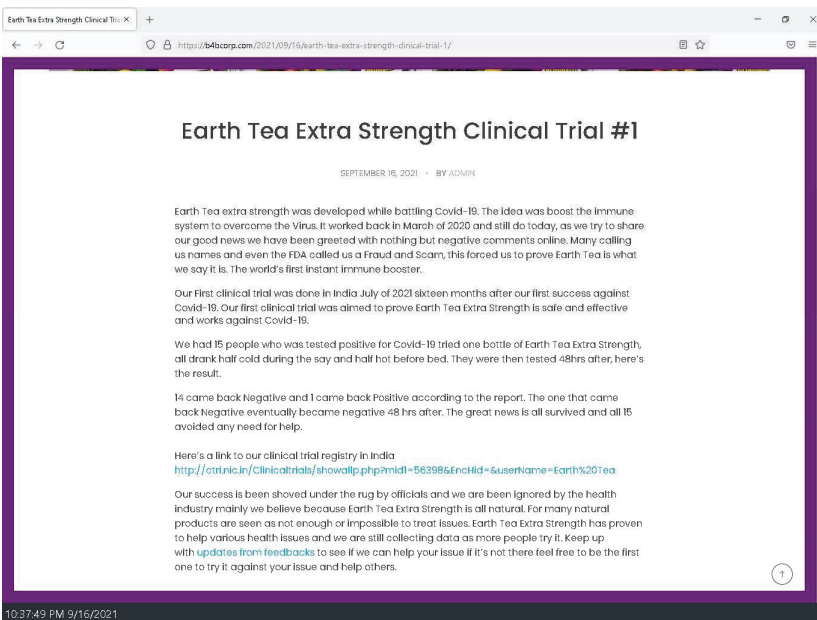


“B4BCorp is sharing a COVID-19 Update....Earth Tea works!! The all natural instant immune booster clinical trial proves its effective against Covid19.”

Website b4bcorp.com (captured 09.16.21)

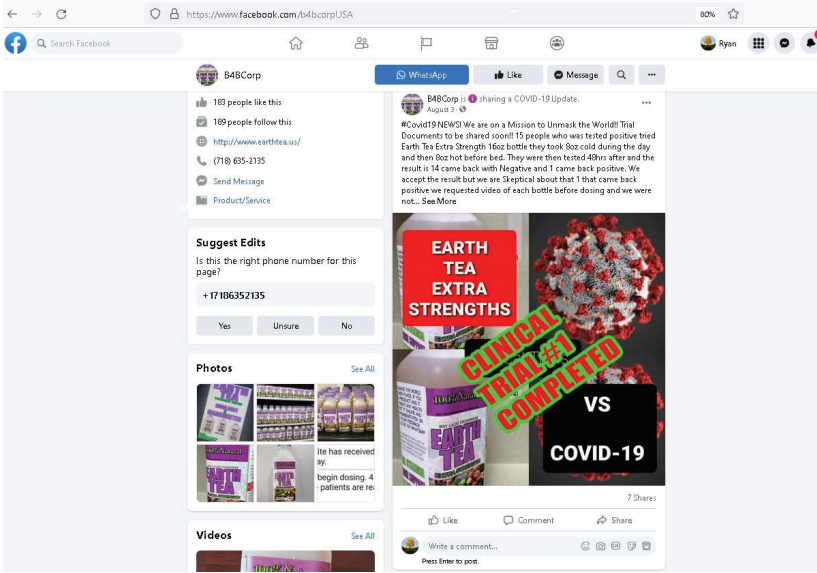


“Our Clinical Trial was successful. So successful we are offering Money Back Guarantee against covid-19 if 2 bottles do not get you negative you will get your money back!”



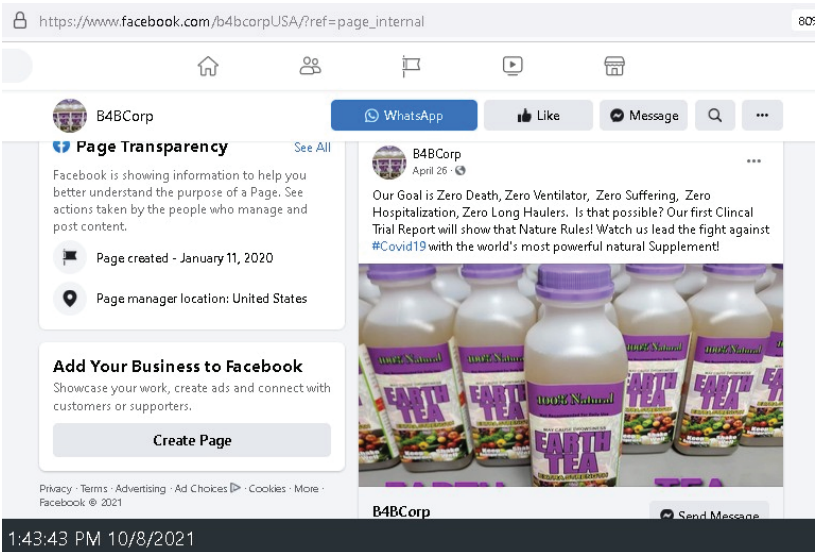
“Our First clinical trial was done in India in July of 2021 sixteen months after our first success against Covid-19... to prove Earth Tea Extra Strength is safe and effective and works against Covid-19. We had 15 people who was tested positive for Covid-19 tried one bottle of Earth Tea Extra Strength.... They were then tested 48 hrs after, here’s the result. 14 came back Negative and 1 came back Positive.... The great news is all survived and all 15 avoided any need for help.”

Facebook b4bcorpUSA Aug. 3, 2021 (captured 10.20.21)



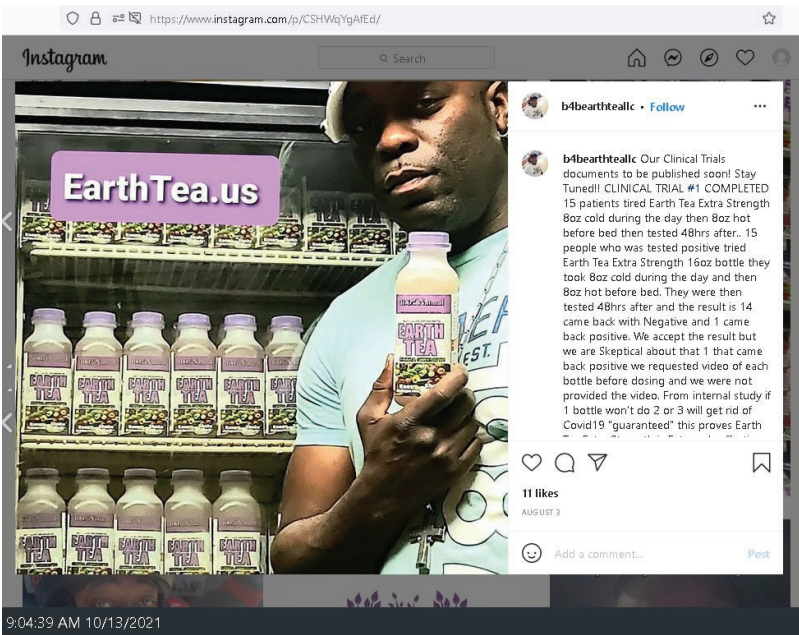
“Covid19NEWS! We are on a Mission to Unmask the World!! Trial documents to be shared soon!! 15 people who tested positive tried Earth Tea Extra Strength 16 oz bottle they took 8 oz cold during the day and then 8 oz hot before bed. They were then tested 48 hours after and the result is 14 came back with Negative and 1 came back positive.”

Facebook b4bcorpUSA April 26, 2021 (captured 10.8.21)



“Our Goal is Zero Death, Zero Ventilator, Zero Suffering, Zero Hospitalization, Zero Long Haulers. Is that possible? Our first Clinical Trial Report will show that Nature Rules! Watch us lead the fight against #Covid19 with the world’s most powerful natural Supplement!”

Instagram b4bearhteallc Aug. 3, 2021 (captured 10.13.2021)

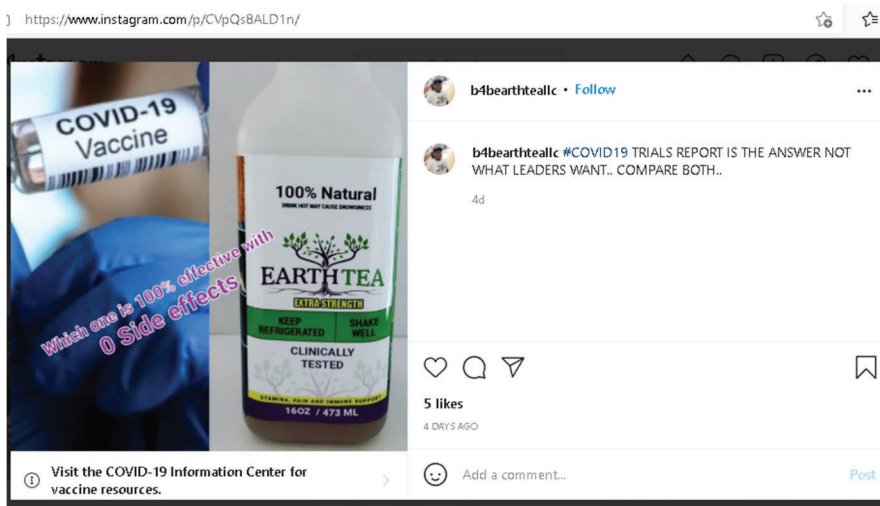


“Our clinical Trials documents to be published soon! Stay Tuned!!!...15 people who was tested positive tried Earth Tea Extra Strength 16 oz bottle....They were then tested 48 hrs after and the result is 14 came back with Negative and 1 came back positive....From internal study if 1 bottle won't do 2 or 3 will get rid of COVID19 'guaranteed'...”

C. Claims That Earth Tea Is More Effective at Preventing and Treating COVID-19 than Vaccination

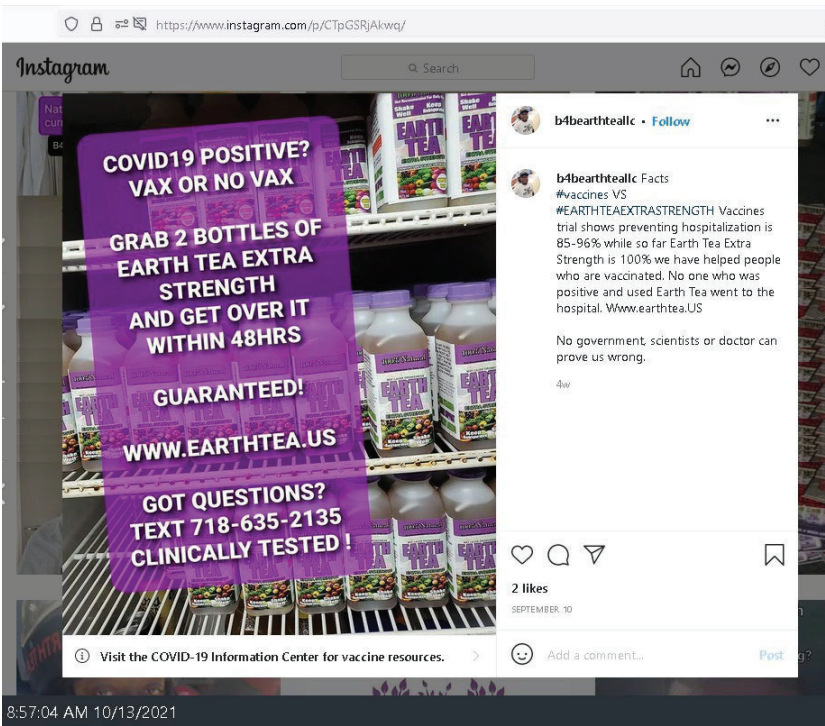
30. Defendants also disseminated or caused to be disseminated claims, including the following, that Earth Tea is more effective than vaccination at preventing or treating COVID-19.

Instagram b4bearhteallc Oct. 31, 2021 (captured 11.03.2021)



[Picture of vial labeled “COVID-19 Vaccine” and a bottle of Earth Tea]
 “Which one is 100% effective with 0 Side effects”
 “#COVID19 TRIALS REPORT IS THE ANSWER NOT WHAT LEADERS WANT.. COMPARE BOTH..”

Instagram b4bearhtealc Sept. 10, 2021 (captured 10.13.21)



“#vaccines
#EARTHTEAEXTRASTRENGTH
Vaccines trial shows preventing hospitalization is 85%-96% while so far Earth Tea Extra Strength is 100% we have helped people who are vaccinated. No one who was positive and used Earth Tea went to the hospital.”

II. Defendants’ Deceptive Health Claims about Their Product are Harming Consumers

31. Defendants deceptively advertise that Earth Tea prevents or treats COVID-19, and that its efficacy is superior to the current COVID-19 vaccines.

32. Such baseless claims of health benefits are material, because, as prominent claimed benefits of Earth Tea, they are plainly a primary reason that anyone would pay \$60 to purchase a bottle of Earth Tea.

33. Upon information and belief, Defendants have earned a substantial amount of money from sales of its Earth Tea product during the pandemic, indicating that Defendants’ unsubstantiated claims of efficacy against COVID-19 have led to consumers buying the product.

34. In addition, Defendants’ claims may cause consumers to ingest Earth Tea in lieu of other measures to prevent COVID-19, such as getting vaccinated, social distancing, and

wearing a mask. In fact, the following statements, excerpted from the examples of Defendants' advertising provided above, appear to encourage this:

"Vax [vaccinated] or Not DON'T DIE FROM COVID19. Protect yourself and your family. We are 100% sure we can save you!" (Facebook b4bcorpUSA posted Sept. 3, 2021);

"COVID19 POSITIVE? VAX OR NO VAX GRAB 2 BOTTLES OF EARTH TEA EXTRA STRENGTH AND GET OVER IT WITHIN 48HRS" (Instagram b4bearhteallc posted Sept. 10, 2021);

"COVID19NEWS! We are on a Mission to Unmask the World!!" (Facebook b4bcorpUSA posted Aug. 3, 2021);

"Vaccines trial shows preventing hospitalization is 85%-96% while so far Earth Tea Extra Strength is 100%" (Instagram b4bearhteallc posted Sept. 10, 2021).

IV. Defendants Refuse to Cease Deceptive Advertising Despite Notice from FTC and FDA

35. Defendants have continued to make these and other deceptive and unsubstantiated claims about Earth Tea despite multiple written warnings from FTC and FDA that such conduct violates the law and may lead to legal action by the government.

36. A February 18, 2021 warning letter issued jointly by the FTC and the FDA informed Defendant B4B Corp. that its b4bcorp.com website and its b4bcorpUSA Twitter account were unlawfully advertising Earth Tea for the mitigation, prevention, treatment, diagnosis or cure of COVID-19, including by making the following claims about Earth Tea: "confirmed to stop coughing from Covid-19 100%"; "#1 choice to get people off the #ventilator not only for

covid19 but in general”; “our official formula now 100% guarantee to get rid of #Covid19”; and “the most effective Treatment against #COVID19.” Complaint, Ex. A (Feb. 18, 2021 warning ltr.) at 4. The warning letter stated, in part:

It is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product or service can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the product identified above [Earth Tea]. Thus, any coronavirus-related prevention claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims.

37. In the warning letter, FDA also informed Defendants that the Earth Tea “product is an unapproved new drug” and “a misbranded drug” in violation of the FDCA. Ex. A at 2. The Warning Letter explained: “FDA considers your product(s) referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States.” Ex. A at 4. The warning letter further stated that failure to correct the violations could result in legal action, including an injunction. Ex. A at 3.

38. Defendant Sinclair responded to the February 18, 2021 warning letter on February 19, 2021 and to subsequent communications with FTC staff. Subsequently, Defendants removed their claims of Earth Tea’s efficacy against COVID-19 from their websites and social media accounts. In March 2021, FDA and FTC indicated to Defendants that it appeared that Defendants had addressed the violations included in the warning letter. FDA’s letter to this effect also reminded Defendants that they had a continuing responsibility to comply with the FDCA and other relevant legal authority.

39. By April 2021, however, Defendants had resumed making claims that Earth Tea

could prevent, mitigate, treat and cure COVID-19 and added claims that these health benefits were purportedly backed by a clinical trial. On September 29, 2021, FTC staff emailed Defendant Sinclair to inform him that Defendants' express and implied claims about the benefits of Earth Tea for COVID-19 were unsubstantiated and violated both the FTC Act and the COVID-19 Consumer Protection Act ("CCPA"). Defendants kept making such claims despite this warning.

40. To date, Defendants have not received approval for a NDA, ANDA, or IND Application¹ for Earth Tea, and they continue to cause the distribution of this unapproved new drug in interstate commerce. Accordingly, unless restrained by this Court, Defendants will continue to violate the FDCA, 21 U.S.C. § 331(d), in the manner set forth above.

41. Based on the facts and violations of law alleged in this Complaint, the United States has reason to believe that Defendants are violating or are about to violate FTC and FDA laws enforced by the United States. Among other reasons, Defendants have engaged in their unlawful acts and practices willfully and knowingly despite being clearly advised of their illegality in the joint FDA/FTC warning letter and in subsequent communications with FTC staff in February and March of 2021. Although Defendants may have briefly discontinued deceptive and false claims about the benefits of Earth Tea for COVID-19, they have resumed their unlawful acts and practices and continue such practices despite additional communications from

¹ An NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. An ANDA contains data which is submitted to FDA for the review and potential approval of a generic drug product. An IND application is submitted by applicants who propose to study an unapproved drug or an approved product for a new indication or in a new patient population, or who seek authorization for the use of an experimental drug in an emergency situation or for serious or immediately life-threatening conditions.

FTC staff on September 29, 2021, showing that permanent injunctive relief is necessary and appropriate.

COUNT ONE

FTC Act Section 5(a) and Section 12 Violations

42. Paragraphs 1 through 42 are incorporated as if set forth herein.

43. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Earth Tea, including through the statements reflected above, Defendants have represented, directly or indirectly, expressly or by implication, that Earth Tea:

- a. prevents COVID-19;
- b. treats the symptoms of COVID-19;
- c. cures COVID-19;
- d. leads to recovery from COVID-19 within 48 hours;
- e. is 100% effective in preventing hospitalization from COVID-19;
- f. is more effective than a vaccine in preventing hospitalization from COVID-19;
- g. is clinically proven effective to treat and cure COVID-19; and
- h. is clinically proven to cure COVID-19 in 48 hours.

44. The foregoing representations are false or misleading, or were not substantiated at the time the representations were made.

45. In truth and in fact, Defendants have no competent and reliable scientific evidence that any of Defendants' statements identified in Paragraph 43(a)-(h) are true.

46. Therefore, the making of the representations as set forth in Paragraph 43 of this

Complaint constitutes a deceptive act or practice and the making of false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

47. Defendants committed the violations set forth in Paragraph 43 with the knowledge required by Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. § 45(m)(1)(A).

48. Defendants' representations are material to consumers because they relate to COVID-19 prevention and treatment, subjects that are very important to many consumers.

49. Upon information and belief, Defendants continue to make similar misrepresentations regarding the efficacy of Earth Tea for preventing or treating COVID-19.

50. Upon information and belief, consumers are suffering, have suffered, and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act. Upon information and belief, absent injunctive relief by this Court, Defendants are likely to continue to injure consumers and harm the public interest.

COUNT TWO

COVID-19 Consumer Protection Act Violations

51. Paragraphs 1 through 51 are incorporated as if set forth herein.

52. In numerous instances since December 27, 2020, Defendants have made false, misleading, or unsubstantiated representations that Earth Tea is effective for the prevention or treatment of COVID-19.

53. In support of their advertising, marketing, promotion, offering for sale, or sale of Earth Tea, Defendants have represented, directly or indirectly, expressly or by implication, that there is a causal connection between Earth Tea and the prevention or treatment of COVID-19, including claims that Earth Tea:

- a. prevents COVID-19;
- b. treats the symptoms of COVID-19;
- c. cures COVID-19;
- d. leads to recovery from COVID-19 within 48 hours;
- e. is 100% effective in preventing hospitalization from COVID-19;
- f. is more effective than a vaccine in preventing hospitalization from COVID-19;
- g. is clinically proven effective to treat and cure COVID-19; and
- h. is clinically proven to cure COVID-19 in 48 hours.

54. Defendants' representations are false or misleading, or were not substantiated at the time the representations were made.

55. Defendants' representations are material to consumers' decisions.

56. Defendants have been aware of the COVID-19 Consumer Protection Act since at least on or about February 18, 2021.

57. Upon information and belief, Defendants continue to make similar misrepresentations regarding the efficacy of Earth Tea for treating or preventing COVID-19.

58. These ongoing false, misleading, or unsubstantiated representations constitute deceptive acts or practices in violation of Section 5(a) of the FTC Act, § 45(a).

59. Therefore, these representations also constitute deceptive acts or practices in violation of Section 1401(b)(1) of the COVID-19 Consumer Protection Act.

60. Each dissemination of an advertisement that makes deceptive COVID-19-related representations is a separate violation of the COVID-19 Consumer Protection Act subject to civil

penalties.

61. On January 31, 2020, Health and Human Services Secretary Alex M. Azar II, pursuant to his authority under Section 319 of the Public Health Service Act, declared that COVID-19 had caused a public health emergency, which remained in effect throughout the activities detailed in this Complaint and beyond.

62. Enacted on December 27, 2020, the CCPA makes it unlawful, for the duration of the public health emergency declared on January 31, 2020 pursuant to Section 319 of the Public Health Service Act, for any person, partnership, or corporation to “engage in a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the [FTC] Act (15 U.S.C. 45(a)) that is associated with . . . the treatment, cure, prevention, mitigation, or diagnosis of COVID-19.” Pub. L. 116-260, 134 Stat 1182, Title XIV, Section 1401(b)(1).

63. The CCPA provides that “[a] violation of subsection (b) shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under Section 18(a)(1)(B) of the [FTC] Act.” 15 U.S.C. § 57a(a)(1)(B).

64. Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. § 45(m)(1)(A), as modified by Section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, as amended, and as implemented by 16 C.F.R. § 1.98(d), authorizes this Court to award monetary civil penalties of up to \$46,517 for each violation of Section 5(a) of the FTC Act pursuant to the CCPA, 16 C.F.R. § 1.98(d).

65. Upon information and belief, consumers are suffering, have suffered, and will continue to suffer substantial injury as a result of Defendants’ violations of the FTC Act and the COVID-19 Consumer Protection Act. Upon information and belief, absent injunctive relief by

this Court, Defendants are likely to continue to injure consumers and harm the public interest.

COUNT THREE

Federal Food, Drug, and Cosmetic Act Violations

66. Paragraphs 1 through 66 are incorporated as if set forth herein.

67. Defendants' Earth Tea products are drugs within the meaning of the FDCA, because they are in intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. According to Defendants' statements about Earth Tea and their promotion, advertising, and labeling of the Earth Tea product, including but not limited to the websites b4bearhteallc.com and b4bcorp.com and postings on TikTok, Twitter, Instagram and YouTube, Earth Tea is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of COVID-19 in man.

68. Earth Tea is not generally recognized as safe and effective for its intended uses, because there are no published adequate and well-controlled clinical studies demonstrating that Earth Tea is generally recognized as safe and effective for its intended uses, nor is it the subject of safety investigations resulting in such recognition, nor has it been used for a material extent or time under such conditions. Therefore, Earth Tea is a new drug within the meaning of 21 U.S.C. § 321(p).

69. A drug that is a "new drug" within the meaning of the FDCA is prohibited from being introduced or delivered for introduction into interstate commerce unless FDA has approved NDA or ANDA for that drug, or the drug is exempt from approval. *See* 21 U.S.C. §§ 355(a), (b), (i), and (j).

70. FDA has received no new drug applications or abbreviated new drug applications,

or investigational new drug applications for Defendants' Earth Tea. Defendants' products are therefore unapproved new drugs within the meaning of 21 U.S.C. §355(a) and are not exempt from the FDCA's approval requirements for new drugs.

71. Defendants violate 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.

72. Upon information and belief, Defendants have caused the distribution of Earth Tea products nationwide, including, but not limited to, shipment of Earth Tea products from New York to Virginia. Such shipment constitutes the introduction or delivery for introduction of unapproved new drugs into interstate commerce under 21 U.S.C. § 331(d).

PRAYER FOR RELIEF

73. WHEREFORE, the United States, pursuant to Sections 5(a)(1), 5(m)(1)(A), 13(b), 16(a)(1), and 19 of the FTC Act, 15 U.S.C. §§ 45(a)(1), 45(m)(1)(A), 52, 53(b), 56(a)(1), and 57b, the COVID-19 Consumer Protection Act, Public Law 116-260, 134 Stat. 1182, Title XIV, Section 1401(c)(2)(A) of the COVID-19 Consumer Protection Act, the FDCA, 21 U.S.C. § 332(a), and the Court's own equitable powers, requests that the Court:

A. Enter a permanent injunction to prevent future violations of the FTC Act, the COVID-19 Consumer Protection Act, and the FDCA by the Defendants;

B. Award such relief pursuant to Section 19 of the FCT Act as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of Section 5 of the FTC Act pursuant to the COVID-19 Consumer Protection Act, including rescission or

reformation of contracts, the refund of money or return of property, the payment of damages, and public notification respecting the unfair or deceptive act or practice;

C. Award Plaintiff monetary civil penalties from Defendants for every violation of the COVID-19 Consumer Protection Act alleged in this Complaint;

D. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly violating the FDCA, 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce unapproved new drugs.

E. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly violating the FDCA in any way, including by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any drug, including but not limited to the Earth Tea products and any product labeled similarly to such products and containing the same active ingredients, unless and until an approved NDA, ANDA, or an IND application Defendants filed pursuant to 21 U.S.C. § 355(b), (j), or (i), is in effect for such drugs, or Defendants have removed all statements or information from their product labels, labeling, promotional materials, websites owned or controlled by or related to any Defendant, and in any other media that cause any of Defendants' products to be drugs within the meaning of the FDCA.

F. Order that FDA be authorized to inspect Defendants' place(s) of business and

all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any of Defendants' products to ensure continuing compliance with the terms of the injunction and the FDCA, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

G. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court determines to be just and proper.

Dated: 3/3/2022

FOR THE UNITED STATES OF AMERICA:

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