IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. **PICK AND PAY, INC./ CILI MINERALS, LLC, a corporation, and ANTON S. BOTHA, an individual,** Defendants.	CIVIL ACTION NO. 6:17-cv-279 JUDGE MAG. JUDGE **COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

SUMMARY OF THE ACTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act" or "FDCA"), 21 U.S.C. § 332(a), to enjoin and restrain Pick and Pay, Inc./ Cili Minerals, LLC ("Cili Minerals" or the "company"), a corporation, and Anton S. Botha, an individual (collectively, "Defendants"), from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce a new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355, nor exempt from approval;

b. 21 U.S.C. § 331(a), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

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

d. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), and misbranded within the meaning of 21 U.S.C. §§ 343(e)(1) & 343(q)(5)(F);

e. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), and misbranded within the meaning of 21 U.S.C. §§ 343(e)(1) & 343(q)(5)(F), while such articles are held for sale after shipment of one or more of their components in interstate commerce; and

f. 21 U.S.C. § 331(dd), by failing to maintain a food (dietary supplement) facility registration for the firm's facility that is engaged in manufacturing, processing, packing, or holding food, as required by 21 U.S.C. § 350d(a).

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345, and its inherent equitable authority, and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Cili Minerals is a limited liability company, which was incorporated in Louisiana in February 2010. The company's headquarters is located at 600 Guilbeau Road, Suite

C, Lafayette, Louisiana, 70506. The company also manufactures, packs, labels, and distributes its products from a second facility located at 113 Pine Park Drive, Lafayette, Louisiana, 70508 (the "manufacturing facility"). Both of these facilities are within the jurisdiction of this Court. The company operates under several other names, including: Pick and Pay, Inc., dba Cili Minerals, Pick and Pay Hyper, Inc., dba Cili Minerals, Pick and Pay Hyper #2, Cili Minerals International, and Pick and Pay Hyper, dba Cili Minerals. Cili Minerals manufactures, packs, labels, and distributes approximately 40 different products under its own brand name: Cili Minerals. Defendants also operate three websites: www.ciliminerals.com, www.cilihealthstore.com, and www.cil-ergy.com.

5. Defendant Anton S. Botha is the company's President, CEO, sole officer, and owner. He is responsible for purchasing and manufacturing materials, purchasing equipment, and overseeing product quality, sales, and distribution. He also develops the content for the company's websites and other product labeling. During FDA's January 2016 inspection, Mr. Botha identified himself to the FDA investigators as the person most responsible for the company. Mr. Botha performs his duties at both of Cili Minerals' locations in Lafayette, Louisiana, within the jurisdiction of this Court.

6. Defendants manufacture, pack, label, and distribute many products, including, but not limited to: ADD-Ease, Bone Structure, CilZinCo, Calcium, Boron, Potassium, Cilver, Sulfur, and Germanium. Components of these products, including Potassium Chloride, Potassium Sulfate, and Sodium Selenite, are shipped to Louisiana from an out-of-state supplier from its facilities in California and New Jersey.

7. Defendants sell their products directly to consumers and to wholesalers located in Ohio, California, Texas, Rhode Island, Florida, and Massachusetts, among other states.

Defendants also operate a retail store at their headquarters, located at 600 Guilbeau Road, Suite C, Lafayette, Louisiana. Defendants also sell a small percentage of their products to consumers located throughout the United States through telephone orders using the phone number listed on their website, www.cil-ergy.com.

DEFENDANTS' PRODUCTS ARE DRUGS UNDER THE ACT

8. Under the Act, a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

9. The intended use of a product may be determined from any relevant source, including labeling and other promotional materials. 21 C.F.R. § 201.128.

10. 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).

11. Defendants promote some of their products in product labeling for the cure, mitigation, treatment, and prevention of various diseases, including cancer, cardiovascular disease, osteoporosis, depression, epilepsy, arthritis, and Multiple Sclerosis, among others. For example, Defendants' website, www.cil-ergy.com, includes the following disease treatment claims:

a. Boron: "Boron . . . helps prevent osteoporosis, arthritis, and tooth decay."

b. Calcium: "Calcium lowers cholesterol levels and helps prevent cardiovascular disease."; "This important mineral [(Calcium)] is also essential in blood clotting and helps prevent cancer."

c. Cilver or [S]ilver: "SOME SYMPTOMS OF A SILVER DEFICIENCY AND SOME DISEASES WHERE THE USE OF SILVER MAY BE BENEFICIAL: Anthrax,

Athlete's foot, Boils, Candida, Colitis, Cystitis, Cerebro-spinal meningitis, Dermatitis, Diphtheria, Diplococcus, Dysentery, E. coli . . ."

d. Germanium: "[I]ntake of germanium improved many illnesses, including rheumatoid arthritis…elevated cholesterol, candidiasis, chronic viral infections, cancer, and AIDS."

e. Potassium: "Potassium…aids rheumatic or arthritic conditions (causes acids to leave joints and ease stiffness) …a natural pain desensitizer, helps control convulsions, headaches and migraines, promotes faster healing of cuts, bruises & other injuries…"

f. Sulfur: "It also helps…alleviate much of the pain and stiffness associated with the more and more common conditions of arthritis, osteoporosis, carpal tunnel syndrome, lower back pain, etc."; "Many suffering from Multiple Sclerosis (MS) are helped by sulfur."

12. Based on these claims, and many others found on Defendants' website, these products and others promoted and distributed by Defendants are drugs under the Act.

DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS

13. A "new drug" is defined as any drug "the composition of which is such that the 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). For a product to be deemed "generally recognized as safe and effective" ("GRAS/E"), it must have substantial evidence of safety and effectiveness. 21 U.S.C. § 355(d). If it is an over-the-counter ("OTC") drug, the product must comply with a monograph established pursuant to an FDA regulation. 21 C.F.R. § 330.1.

14. Under the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval. 21 U.S.C. §§ 355(a), (b), (j); 331(d). A drug may be exempt from the Act's new drug approval requirements, 21 U.S.C. § 355(a), if it is the subject of an investigational new drug application ("IND"). 21 U.S.C. § 355(i).

15. Defendants' drugs are "new drugs" as defined by 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of such drugs, as safe and effective for the uses prescribed, recommended, or suggested in their labeling.

16. FDA has searched its records for NDA, ANDA, and IND submissions by Defendants. Defendants have no such approvals on file from FDA. Moreover, Defendants' drugs do not conform to the OTC monograph set forth in 21 C.F.R. § 330.1, or any other OTC drug monograph. As a result, Defendants' drugs may not be distributed legally in interstate commerce. 21 U.S.C. § 331(d).

DEFENDANTS' PRODUCTS ARE MISBRANDED DRUGS

17. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

18. A drug is misbranded if its label fails to bear "adequate directions for use" as defined by 21 C.F.R. § 201.5(a), and it does not fall within a regulatory exemption from that requirement under 21 C.F.R. § 201.115. 21 U.S.C. § 352(f)(1).

19. "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5(a).

20. Defendants drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because they lack adequate and well-controlled studies to support the claims made for them. Their labeling therefore necessarily fails to bear adequate directions for use, and, because they are unapproved new drugs, they are not exempt from that requirement. 21 C.F.R. §§ 201.100(c)(2), 201.115.

21. Some of Defendants' drug products are also prescription drugs because of the purposes for which they are intended, including the self-diagnosis and treatment of cancer, cardiovascular disease, osteoporosis, depression, epilepsy, arthritis, and Multiple Sclerosis, among others. 21 U.S.C. § 353(b)(1)(A). By definition, prescription drugs cannot contain adequate directions for lay use, see id., causing Defendants' prescription drug products to be misbranded under 21 U.S.C. § 352(f)(1).

DEFENDANTS DISTRIBUTE ADULTERATED DIETARY SUPPLEMENTS

22. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of them]." 21 U.S.C. § 321(ff). In addition, a dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." Id.

23. Defendants' products fall within the Act's definition of a dietary supplement. 21 U.S.C. § 321(ff).

24. Although dietary supplements are deemed to be "food" under the Act, 21 U.S.C. § 321(ff), the Act expressly provides that a product that is a dietary supplement may also be a drug if it meets the definition of a "drug" under 21 U.S.C. § 321(g).

25. The Act requires manufacturers of dietary supplements to operate in compliance with current good manufacturing practice regulations for dietary supplements set forth at 21 C.F.R. Part 111 ("Dietary Supplement cGMP"). 21 U.S.C. § 342(g)(1). Dietary supplements not manufactured, prepared, packed, or held in conformance with Dietary Supplement cGMP are deemed to be adulterated. 21 U.S.C. § 342(g)(1).

26. FDA first inspected Defendants manufacturing facility between November 26 and 30, 2012. During that inspection, FDA investigators observed a number of Dietary Supplement cGMP violations, including, but not limited to, Defendants' failure to:

a. prepare written master manufacturing records ("MMRs") for each batch size of a dietary supplement manufactured, as required by 21 C.F.R. § 111.205;

b. prepare batch production records ("BPRs") for every batch of dietary supplement manufactured, as required by 21 C.F.R. § 111.255;

c. establish written specifications for finished batches of dietary supplements, as required by 21 C.F.R. § 111.70(e); and

d. verify the identity of dietary ingredients prior to use, as required by 21 C.F.R. § 111.75(a)(1)(a).

27. FDA next inspected Defendants' manufacturing facility from October 20 to 28, 2015. While Defendants demonstrated some improvement from the 2012 inspection, during this inspection, FDA investigators observed Defendants' failure to prepare written MMRs for each batch of dietary supplement manufactured, as required by 21 C.F.R. § 111.205.

28. FDA observed similar violations of dietary supplement cGMP during its third inspection, conducted between November 6 and 19, 2014. For example, FDA investigators

observed during this inspection Defendants' failure to verify the identity of dietary ingredients prior to use, as required by 21 C.F.R. § 111.75(a)(1)(a).

29. FDA investigators most recently inspected Defendants' manufacturing facility from January 19 – 22, 2016 (the "January 2016 inspection"). The January 2016 inspection revealed significant deviations from Dietary Supplement cGMP, including many repeat observations from FDA's three previous inspections. These observations include, but are not limited to, Defendants' failure to:

a. Prepare adequate written MMRs for each unique dietary supplement formulation, as required by 21 C.F.R. § 111.205;

b. Prepare adequate BPRs, as required by 21 C.F.R. § 111.255(a);

c. Establish specifications for, among others, dietary supplement components, packaging and labeling, and finished batches, as required by 21 C.F.R. § 111.70(b), (d), (e), and (g);

d. Test their dietary ingredient components and finished products to verify that they meet specifications, as required by 21 C.F.R. §§ 111.73 and 111.75(a)(1);

e. Verify that the finished dietary supplement batches meet product specifications for identity, purity, strength, or composition, as required by 21 C.F.R. § 111.75(c); and,

f. Test the dietary ingredient components, non-dietary ingredient components, and finished product dietary supplements to verify that they meet specifications, as required by 21 C.F.R. §§ 111.73, 111.75(a)(1)(i), and 111.75(a)(2).

30. As a result of their Dietary Supplement cGMP violations, the dietary supplements manufactured by Defendants are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

31. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce dietary supplements that are adulterated.

32. Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements to become adulterated while such dietary supplements are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS DISTRIBUTE MISBRANDED DIETARY SUPPLEMENTS

33. Dietary supplements are misbranded if they fail to identify on the label the manufacturer, packer, or distributor's name and business. 21 U.S.C. § 343(e)(1); see 21 C.F.R. § 101.5. Specifically, Defendants' dietary supplements fail to bear the Cili Minerals' name or place of business.

34. Dietary supplements are also misbranded if they fail to list the nutrition information in the Supplement Facts panel in accordance with 21 U.S.C. § 343(q)(5)(F). See 21 C.F.R. §§ 101.36(b)(2)(i)(A)-(B); 101.36(b)(3)(i). For example, the Bone Structure label declares mineral ingredients by parts per million rather than by weight, and the Bone Structure and CilZinCo labels fail to properly list ingredients.

35. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce dietary supplements that are misbranded.

36. Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements to become misbranded while such dietary supplements are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS FAILED TO PROPERLY REGISTER

37. The Act prohibits the failure of a food (dietary supplement) facility engaged in manufacturing, processing, packing, or holding food to register in accordance with 21 U.S.C. § 350d. 21 U.S.C. § 331(dd). Once registered, a food facility is required to renew its registration each even-numbered year. 21 U.S.C. § 350d(a)(3).

38. Defendants violate 21 U.S.C. § 331(dd) in that they have not renewed their registration for their manufacturing facility located at 113 Pine Park Drive, Lafayette, Louisiana since they registered this address in March 1, 2010.

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

39. Defendants ship their finished drug and dietary supplement products in interstate commerce to locations outside of Louisiana, including Ohio, California, Texas, Rhode Island, Florida, and Massachusetts. Such shipments constitute the introduction or delivery for introduction into interstate commerce within the meaning of 21 U.S.C. §§ 331(a) and (d).

40. Defendants' conduct also satisfies the interstate commerce element under 21 U.S.C. § 331(k), because Defendants manufacture their drug and dietary supplement products using components that are shipped in interstate commerce from places outside of the state of Louisiana. For example, during the January 2016 inspection, the FDA investigators collected records that documented Defendants' receipt of ingredients, including Potassium Chloride, Potassium Sulfate, and Sodium Selenite, from an out-of-state supplier that ships components to Defendants from its facilities in California and New Jersey.

HISTORY

41. Defendants are well aware that their conduct violates the law and that continued violations could result in this injunction. FDA has inspected Defendants four times, and found the same or similar violations each time.

42. FDA first inspected Defendants' manufacturing facility in November 2012. At the close of this inspection, FDA investigators issued Cili Minerals and Mr. Botha a 14-item List of Inspectional Observations ("Form FDA 483") listing numerous Dietary Supplement CGMP violations, including, but not limited to Defendants' failure to: (a) prepare written MMRs for each batch size of a dietary supplement manufactured; (b) prepare written BPRs for every batch of dietary supplement manufactured; (c) establish written specifications for finished batches of dietary supplements; and (d) verify the identity of dietary ingredients prior to use. FDA investigators discussed these violations with Mr. Botha at the conclusion of the 2012 inspection.

43. Mr. Botha and his consultant met with representatives from FDA's New Orleans District Office on November 23, 2013, to discuss the November 2012 observations and other FDCA violations, including claims in Defendants' labeling which caused Defendants' products to be unapproved new drugs and misbranded drugs.

44. FDA next inspected Defendants' manufacturing facility in November 2014 and issued Cili Minerals and Mr. Jeremy Tezeno, the company's former Manager who reported directly to Defendant Botha, another FDA Form 483 listing the same or similar Dietary Supplement cGMP violations as the previous inspection. In particular, FDA observed Defendants' failure to verify the identity of dietary ingredients prior to use. FDA investigators again reminded Defendants to renew their facility registration, which expired at the end of December 2012. The FDA investigators also discussed these violations with Mr. Tezeno at the close of the inspection.

45. On May 8, 2015, based on the November 2014 observations and a review of the company's website, www.cilihealthstore.com, FDA issued a Warning Letter to Cili Minerals and Mr. Botha. The Warning Letter notified the company and Mr. Botha that their practices violated

the Act and its regulations. Specifically, FDA warned that Cili Minerals was distributing unapproved new drugs and misbranded drugs, as well as adulterated and misbranded dietary supplements. FDA also warned that continued violations could result in regulatory action, including an injunction or seizure under the FDCA, 21 U.S.C. §§ 332(a), 334.

46. Mr. Botha responded to FDA's Warning Letter, in an email dated May 31, 2015, claiming that he had disabled his website, www.cilihealthstore.com, corrected a number of the cGMP violations, and was retaining a consultant to help him re-label his products.

47. Despite Mr. Botha's promises, on May 31, 2015 an undercover FDA investigator was able to purchase unapproved new drugs from another of Defendants' websites, www.cil-ergy.com.

48. FDA investigators most recently returned to the company's manufacturing facility in October 2015 and January 2016 and again found significant violations, issuing a 6 and 8-item Forms FDA 483, respectively, listing Dietary Supplement cGMP violations at the close of each inspection. The FDA investigators discussed these violations with Mr. Botha and Mr. Tezeno at the conclusion of each respective inspection, and also reminded them again to renew their facility registration, which expired at the end of December 2012. To date, Defendants have not renewed their manufacturing facility registration with FDA.

49. Defendants' continued failure to come into compliance with the Act and its implementing regulations demonstrates their unwillingness or inability to comply with the law absent an injunction. Based on Defendants' conduct, it is evident that, unless restrained by order of this Court, Defendants will continue to violate the Act, 21 U.S.C. § 331(a), (d), (k), and (dd).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

I. 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, assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(d), by distributing unapproved new drugs in interstate commerce;

B. Violating 21 U.S.C. § 331(a), by distributing misbranded drugs in interstate commerce;

C. Violating 21 U.S.C. § 331(k), by causing drugs to become misbranded, while such drugs are held for sale after shipment of one or more of their components in interstate commerce;

D. Violating 21 U.S.C. § 331(a), by distributing adulterated and misbranded dietary supplements in interstate commerce;

E. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated and misbranded, while such articles are held for sale after shipment of one or more of their components in interstate commerce; and

F. Violating 21 U.S.C. § 331(dd), by failing to renew the facility registration for the company's manufacturing facility located at 113 Pine Park Drive, Lafayette, Louisiana;

II. 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,

assigns, and any and all persons in active concert or participation with any of them, from distributing any drug or dietary supplement unless and until:

A. A new drug application or abbreviated new drug application is approved and in effect for the product pursuant to 21 U.S.C. § 355; or

B. An investigational new drug exemption is filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

C. Defendants have removed all claims from (1) websites owned, controlled by, or related to Defendants, including, but not limited to Defendants' current websites (www.ciliminerals.com, www.cilihealthstore.com, and www.cil-ergy.com) (collectively, "Defendants' websites"); and (2) any other source that causes Defendants' products to be drugs as defined by the Act;

III. 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 manufacturing, processing, packing, labeling, holding, or distributing dietary supplements, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold dietary supplements are established, operated, and administered in conformity with the Act and Dietary Supplement cGMP, 21 C.F.R. Part 111, in a manner acceptable to FDA;

B. Defendants have updated their labeling to ensure that the labeling on all dietary supplements is in compliance with 21 U.S.C. §§ 343(e)(1) & 343(q)(5)(F); and

C. Defendants have renewed their registration for their manufacturing facility, in compliance with 21 U.S.C. § 350d;

IV. Order that FDA be authorized under this injunction to inspect Defendants' facilities and all records relating to receiving, manufacturing, processing, packing, labeling, holding, and distributing any drug or dietary supplement to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

V. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 16th day of February, 2017.

Respectfully submitted,

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