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UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEVADA

UNITED STATES OF AMERICA Plaintiff, v. AFFINITYLIFESTYLES.COM, INC., and REAL WATER, INC., corporations, and BRENT A. JONES and BLAIN K. JONES, individuals. Defendants.	Case No. 21-cv-959 COMPLAINT FOR A PERMANENT INJUNCTION

Plaintiff, the United States of America, on behalf of the United States Food and Drug Administration ("FDA") alleges:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 332(a), to halt the manufacture and distribution of adulterated and/or misbranded bottled drinking water and chemical concentrate. Defendants' bottled drinking water has been associated with five cases of acute liver failure in children. Plaintiff seeks an injunction to restrain and enjoin Defendants from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States, and not doing so in compliance with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g;

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) and/or misbranded within the meaning of 21 U.S.C. § 343(i)(2); and

C. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) and/or misbranded within the meaning of 21 U.S.C. § 343(i)(2).

JURISDICTION AND VENUE

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

3. Venue in this district is proper under 28 U.S.C. § 1391.

THE PARTIES

4. Plaintiff, the United States of America, brings this action on behalf of FDA, the agency mandated to protect the public health by, among other things. ensuring the safety of the U.S. food supply, including, but not limited to, bottled drinking water.

5. Defendant AffinityLifestyles.com, Inc. ("Affinity") is a Nevada corporation operating under Nevada Business ID, NV19981130088, and located at 3773 Howard Hughes Parkway, Suite 500S, Las Vegas, Nevada 89169. Affinity is the majority shareholder of Defendant Real Water, Inc.

6. Defendant Real Water, Inc. ("Real Water") is a Delaware corporation, doing business in Nevada, under Nevada Business ID, NV20181191189, with addresses at 3208 W. Desert Inn Rd, Las Vegas, NV 89102 and 6018 E. Main Street, Mesa, Arizona 85205.

7. Real Water manufactures bottled drinking water and a proprietary chemical concentrate ("E^2 Concentrate") at 1180 Center Point Drive, Suite 200, Henderson, Nevada 89102 (the "Henderson Facility"), within the jurisdiction of this Court.

8. Real Water also manufactures bottled drinking water at 6018 E. Main Street, Mesa, Arizona 85205 (the "Mesa Facility").

9. Defendants distribute bottled drinking water from the Henderson Facility and the Mesa Facility under the brands "Re^{2}al Water Drinking Water" and "Re^{2}al Alkalized Water," respectively. "Re^{2}al Water" is used herein to refer to either brand of Defendants' bottled drinking water.

10. Defendants repackage E^2 Concentrate at the Mesa Facility and distribute it under the brand "Re^{2}al Alkalized Water Concentrate."

11. Defendant Brent A. Jones is the President and Director of Affinity and Real Water. He is responsible for purchasing, marketing, and sales at Real Water. Brent A. Jones is a resident of Nevada, who performs his duties at the Henderson Facility, within the jurisdiction of this Court.

12. Defendant Blain K. Jones is the Vice President, Secretary, and Treasurer of Real Water, and the Secretary and Treasurer of Affinity. He is responsible for manufacturing, distribution, and employee training at Real Water. Blain K. Jones is a resident of Nevada, who performs his duties at the Henderson Facility, within the jurisdiction of this Court.

13. Upon information and belief, Defendants Brent A. Jones and Blain K. Jones are the only individuals who know the formula for E^2 Concentrate.

14. Upon information and belief, Defendant Blain K. Jones is the sole individual responsible for manufacturing E^2 Concentrate.

DEFENDANTS' PRODUCTS

15. Defendants manufacture, process, prepare, bottle, pack, label, hold, and distribute articles of food within the meaning of 21 U.S.C. § 321(f), namely Re^{2}al Water and E^2 Concentrate.

16. Defendants manufacture E^2 Concentrate at the Henderson Facility using materials shipped from outside Nevada, including potassium hydroxide provided by a chemical company located in Arizona.

17. To manufacture E^2 Concentrate, Defendants first process municipal tap water by carbon filtration, reverse osmosis filtration, ultraviolet light filtration, and ozone filtration, and then Defendants mix this processed water with potassium hydroxide, potassium bicarbonate, and magnesium chloride.

Next, Defendants claim to use a proprietary "ionizer" apparatus to apply an electrical current to this mixture, which allegedly creates positively-charged and negatively-charged solutions. Defendants then discard the positively-charged solution and store the negatively-charged solution as E^2 Concentrate.

18. Defendants use E^2 Concentrate for manufacturing Re^2al Water at the Henderson Facility. Defendants also send E^2 Concentrate to the Mesa Facility for manufacturing Re^2al Water there, and for repackaging the E^2 Concentrate into retail bottles.

19. Defendants manufacture Re^2al Water by adding E^2 Concentrate and potassium hydroxide to municipal tap water that has been processed as described in paragraph 17. Defendants mix these ingredients in a large tank, and then fill containers with this mixture for distribution as Re^2al Water.

20. Defendants distribute 5-gallon containers of Re^2al Water from the Henderson Facility both to customers within Nevada and to customers located outside of Nevada, including Arizona and California. Defendants distribute 500-milliliter (mL), 1-liter (L), 1.5-L, and 1-gallon containers of Re^2al Water from the Mesa Facility to distributors in Arizona, California, and Nevada. Defendants distribute 4-ounce (oz) bottles of E^2 Concentrate from the Mesa Facility to online consumers throughout the United States.

21. Defendants market Re^2al Water as "premium" drinking water that is a "clean," "healthy" alternative to tap water.

22. Defendants market E^2 Concentrate as a taste enhancer that consumers can add to liquids, including, but not limited to, tea, coffee, and wine.

23. Defendants intend for Re^2al Water and E^2 Concentrate to be consumed with no further processing. It is therefore crucial for Defendants to properly manufacture, process, prepare, bottle, pack, hold, and distribute Re^2al Water and E^2 Concentrate to minimize the potential for chemical and microbial contamination and reduce the risk of illness to consumers.

PREVENTIVE CONTROLS REQUIREMENTS

24. The Federal Food, Drug, and Cosmetic Act requires that the owner, operator, or agent in charge of a facility evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, and identify and implement preventive controls to significantly minimize or prevent the

occurrence of those hazards and provide assurances that such food is not adulterated. See 21 U.S.C. § 350g (Hazard analysis and risk-based preventive controls).

25. The hazard analysis and risk-based preventive controls requirements set forth at 21 C.F.R. Part 117, Subpart C ("Human Food Preventive Control Regulations"), implement 21 U.S.C. § 350g, and were promulgated to better protect the public health by, among other things, ensuring the production of safe and sanitary food through hazard analysis and risk-based preventive controls. See 21 U.S.C. § 350g(n)(1)(A). Failure to comply with the Human Food Preventive Control Regulations violates the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. § 331(uu) and 21 C.F.R. § 117.1(b); see also Final Rule, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls in Human Food, 80 Fed. Reg. 55,908 (Sept. 17, 2015).

26. The hazard analysis requirements require the owner, operator, or agent in charge of a food facility to "conduct a hazard analysis to identify . . . known or reasonably foreseeable hazards . . . to determine whether there are any hazards requiring a preventive control" for each type of food manufactured, processed, packed, or held at the facility. 21 C.F.R. § 117.130(a) (Requirement for a hazard analysis); 21 U.S.C. § 350g(b). Hazards can be biological, chemical, or physical, and they can be naturally occurring, unintentionally introduced, or intentionally introduced for purposes of economic gain. See 21 U.S.C. § 350g(b); 21 C.F.R. § 117.130(b) (Hazard identification).

27. The owner, operator, or agent in charge of a food facility must, among other things, identify and implement preventive controls to provide assurances that any hazards requiring a preventive control are significantly minimized or prevented, and the food manufactured, processed, packed, or held by a facility is not adulterated under 21 U.S.C. § 342. See 21 U.S.C. § 350g(c); 21 C.F.R. § 117.135 (Preventive controls).

28. Preventive controls include, as appropriate to the food and facility, process controls, sanitation controls, supply-chain controls, a recall plan, as well as any other controls necessary to provide assurances that the food is not adulterated under 21 U.S.C. § 342. 21 U.S.C. § 350g(c); 21 C.F.R. § 117.135(c).

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