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14 UNITED STATES DISTRICT COURT FOR THE
 15 DISTRICT OF NEVADA

16 UNITED STATES OF AMERICA

17 Plaintiff,

18 v.

19 AFFINITYLIFESTYLES.COM, INC., and REAL
 20 WATER, INC., corporations, and BRENT A.
 21 JONES and BLAIN K. JONES, individuals.

22 Defendants.

Case No. 21-cv-959

COMPLAINT FOR A PERMANENT
INJUNCTION

23 Plaintiff, the United States of America, on behalf of the United States Food and Drug
 24 Administration (“FDA”) alleges:

25 1. This statutory injunction proceeding is brought under the Federal Food, Drug, and
 26 Cosmetic Act, 21 U.S.C. § 332(a), to halt the manufacture and distribution of adulterated and/or
 27 misbranded bottled drinking water and chemical concentrate. Defendants’ bottled drinking water has
 28 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:

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

3 9. Defendants distribute bottled drinking water from the Henderson Facility and the Mesa
4 Facility under the brands “Re²al Water Drinking Water” and “Re²al Alkalized Water,” respectively.
5 “Re²al Water” is used herein to refer to either brand of Defendants’ bottled drinking water.

6 10. Defendants repackage E² Concentrate at the Mesa Facility and distribute it under the
7 brand “Re²al Alkalized Water Concentrate.”

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

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

15 13. Upon information and belief, Defendants Brent A. Jones and Blain K. Jones are the only
16 individuals who know the formula for E² Concentrate.

17 14. Upon information and belief, Defendant Blain K. Jones is the sole individual responsible
18 for manufacturing E² Concentrate.

19 **DEFENDANTS’ PRODUCTS**

20 15. Defendants manufacture, process, prepare, bottle, pack, label, hold, and distribute articles
21 of food within the meaning of 21 U.S.C. § 321(f), namely Re²al Water and E² Concentrate.

22 16. Defendants manufacture E² Concentrate at the Henderson Facility using materials
23 shipped from outside Nevada, including potassium hydroxide provided by a chemical company located
24 in Arizona.

25 17. To manufacture E² Concentrate, Defendants first process municipal tap water by carbon
26 filtration, reverse osmosis filtration, ultraviolet light filtration, and ozone filtration, and then Defendants
27 mix this processed water with potassium hydroxide, potassium bicarbonate, and magnesium chloride.
28

1 Next, Defendants claim to use a proprietary “ionizer” apparatus to apply an electrical current to this
2 mixture, which allegedly creates positively-charged and negatively-charged solutions. Defendants then
3 discard the positively-charged solution and store the negatively-charged solution as E² Concentrate.

4 18. Defendants use E² Concentrate for manufacturing Re²al Water at the Henderson Facility.
5 Defendants also send E² Concentrate to the Mesa Facility for manufacturing Re²al Water there, and for
6 repackaging the E² Concentrate into retail bottles.

7 19. Defendants manufacture Re²al Water by adding E² Concentrate and potassium hydroxide
8 to municipal tap water that has been processed as described in paragraph 17. Defendants mix these
9 ingredients in a large tank, and then fill containers with this mixture for distribution as Re²al Water.

10 20. Defendants distribute 5-gallon containers of Re²al Water from the Henderson Facility
11 both to customers within Nevada and to customers located outside of Nevada, including Arizona and
12 California. Defendants distribute 500-milliliter (mL), 1-liter (L), 1.5-L, and 1-gallon containers of Re²al
13 Water from the Mesa Facility to distributors in Arizona, California, and Nevada. Defendants distribute
14 4-ounce (oz) bottles of E² Concentrate from the Mesa Facility to online consumers throughout the
15 United States.

16 21. Defendants market Re²al Water as “premium” drinking water that is a “clean,” “healthy”
17 alternative to tap water.

18 22. Defendants market E² Concentrate as a taste enhancer that consumers can add to liquids,
19 including, but not limited to, tea, coffee, and wine.

20 23. Defendants intend for Re²al Water and E² Concentrate to be consumed with no further
21 processing. It is therefore crucial for Defendants to properly manufacture, process, prepare, bottle, pack,
22 hold, and distribute Re²al Water and E² Concentrate to minimize the potential for chemical and
23 microbial contamination and reduce the risk of illness to consumers.

24 **PREVENTIVE CONTROLS REQUIREMENTS**

25 24. The Federal Food, Drug, and Cosmetic Act requires that the owner, operator, or agent in
26 charge of a facility evaluate the hazards that could affect food manufactured, processed, packed, or held
27 by such facility, and identify and implement preventive controls to significantly minimize or prevent the
28

1 occurrence of those hazards and provide assurances that such food is not adulterated. See 21 U.S.C.
2 § 350g (Hazard analysis and risk-based preventive controls).

3 25. The hazard analysis and risk-based preventive controls requirements set forth at 21
4 C.F.R. Part 117, Subpart C (“Human Food Preventive Control Regulations”), implement 21 U.S.C.
5 § 350g, and were promulgated to better protect the public health by, among other things, ensuring the
6 production of safe and sanitary food through hazard analysis and risk-based preventive controls. See 21
7 U.S.C. § 350g(n)(1)(A). Failure to comply with the Human Food Preventive Control Regulations
8 violates the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. § 331(uu) and 21 C.F.R. § 117.1(b);
9 see also Final Rule, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive
10 Controls in Human Food, 80 Fed. Reg. 55,908 (Sept. 17, 2015).

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

18 27. The owner, operator, or agent in charge of a food facility must, among other things,
19 identify and implement preventive controls to provide assurances that any hazards requiring a preventive
20 control are significantly minimized or prevented, and the food manufactured, processed, packed, or held
21 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
22 (Preventive controls).

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

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