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14 **UNITED STATES DISTRICT COURT**
15 **DISTRICT OF NEVADA**

16 UNITED STATES OF AMERICA,

17 Plaintiff,

18 v.

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

23 Defendants.

Case No. 21-cv-959-JAD-BNW

**CONSENT DECREE OF PERMANENT
INJUNCTION**

ECF No. 3

24 Plaintiff, the United States of America, on behalf of the United States Food and Drug
25 Administration (“FDA”), by its undersigned attorneys, having filed a Complaint for Injunction
26 (“Complaint”) against Affinitylifestyles.com, Inc., and Real Water, Inc., corporations; and Brent
27 A. Jones and Blain K. Jones, individuals (collectively, “Defendants”), and Defendants having
28 appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the
“Decree”) without contest and without admitting the violations described herein, and before any
testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1 1. This Court has jurisdiction over the subject matter and all parties to this action.

2 2. The Complaint states a cause of action against Defendants under the Federal Food,
3 Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the “Act”).

4 3. Defendants violated 21 U.S.C. § 331(uu), by operating a facility that manufactured,
5 processed, packed, or held food for sale in the United States, and not doing so in compliance
6 with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g.

7 4. Defendants violated 21 U.S.C. § 331(a), by introducing or delivering for introduction
8 into interstate commerce, or causing to be introduced or delivered for introduction into interstate
9 commerce, articles of food that were adulterated within the meaning of 21 U.S.C. § 342(a)(4) in
10 that they have been prepared, packed, or held under insanitary conditions whereby they may
11 have become contaminated with filth, or whereby they may have been rendered injurious to
12 health.

13 5. Defendants violated 21 U.S.C. § 331(k), by causing articles of food that were held for
14 sale after shipment of one or more of their components in interstate commerce to become
15 adulterated under 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under
16 insanitary conditions whereby they may have become contaminated with filth, or whereby they
17 may have been rendered injurious to health.

18 6. Defendants violated 21 U.S.C. § 331(a), by introducing or delivering for introduction
19 into interstate commerce, or causing to be introduced or delivered for introduction into interstate
20 commerce, articles of food that were misbranded within the meaning of 21 U.S.C. § 343(i)(2).

21 7. Defendants violated 21 U.S.C. § 331(k), by causing articles of food that were held for
22 sale after shipment of one or more of their components in interstate commerce to become
23 misbranded within the meaning of 21 U.S.C. § 343(i)(2).

24 8. For the purposes of this Decree, the following definitions shall apply:

25 A. “Defendants’ Facilities” mean the facilities located at 1180 Center Point Drive,
26 Suite 200, Henderson, Nevada, and 6018 E. Main Street, Mesa, Arizona, and/or any other
27 location(s) at which Defendants now or in the future directly or indirectly manufacture, process,
28 prepare, bottle, pack, label, hold, and/or distribute any article of food; and

1 B. “Defendants’ Products” shall refer to Defendants’ “Re2al Water Drinking Water”
2 and “Re2al Alkalized Water” bottled drinking water (together, “Re2al Water”) and “Re2al
3 Alkalized Water Concentrate” chemical concentrate (“E2 Concentrate”), as well as any other
4 article of food that Defendants now or in the future directly or indirectly manufacture, process,
5 prepare, bottle, pack, label, hold, and/or distribute; and

6 C. “CGMP” shall refer to current good manufacturing practice requirements for
7 human food (set forth at 21 C.F.R. Part 117, Subpart B) and bottled drinking water (set forth at
8 21 C.F.R. Part 129).

9 9. Upon entry of this Decree, Defendants and each and all of their directors, officers,
10 agents, representatives, employees, attorneys, successors and assigns, and any and all persons in
11 active concert or participation with any of them (including individuals, partnerships,
12 corporations, subsidiaries, affiliates, and “doing business as” entities) (collectively, “Associated
13 Persons”) who have received actual notice of this Decree by personal service or otherwise, are
14 permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable
15 authority of this Court, from directly or indirectly manufacturing, processing, preparing, bottling,
16 packing, labeling, holding, and/or distributing articles of food at or from Defendants’ Facilities
17 unless and until:

18 A. Defendants retain, at Defendants’ expense, an independent person or persons (the
19 “Food Safety & Preventive Controls (‘PC’) Expert”) who is without any personal or financial
20 ties (other than the retention agreement) to Defendants or their families, who meets the
21 requirements of a preventive controls qualified individual (“PCQI”) as defined in 21 C.F.R. §
22 117.3, and who, by reason of background, training, education, and experience, is qualified: (1) to
23 establish methods, processes, and controls at Defendants’ Facilities to ensure that articles of food
24 are manufactured, processed, prepared, bottled, packed, labeled, held, and distributed in
25 compliance with CGMP; (2) to develop and implement a written Sanitation Plan, a Bottling Plan,
26 and a Food Safety Plan in accordance with 9(B) below; and (3) to inspect Defendants’ Facilities
27 to determine whether Defendants’ methods, processes, and controls are continuously operated
28 and administered in conformity with this Decree, the Act, and its implementing regulations.

1 Defendants shall notify FDA in writing of the identity and qualifications of the Food Safety &
2 PC Expert within two (2) business days after retaining such Food Safety & PC Expert; and

3 B. The Food Safety & PC Expert, in conjunction with Defendants:

4 (1) Review all FDA inspectional observations of deficiencies at Defendants'
5 Facilities from March/April 2021 to the present and develop, to FDA's satisfaction:

6 a. A written Sanitation Plan and Sanitation Standard Operating Procedures
7 (hereafter, "Sanitation Plan") for manufacturing, processing, preparing, packing, holding, and
8 distributing articles of food. Such Sanitation Plan shall ensure that Defendants' manufacturing
9 processes, cleaning and sanitizing operations, monitoring, and corrective actions, protect against
10 the contamination of food and food-contact surfaces and prevent insanitary conditions at
11 Defendants' Facilities, and shall address, but not be limited to, contamination by chemical
12 hazards and environmental pathogens; and

13 b. A written Bottled Water Processing & Bottling Plan (hereafter, "Bottling
14 Plan") for processing, bottling, and holding of bottled drinking water. Such Bottling Plan shall
15 ensure that Defendants' manufacturing and bottling processes, cleaning and sanitizing
16 operations, sampling and sampling analysis, monitoring, and corrective actions, comply with
17 applicable standards, protect against the contamination of bottled drinking water and water-
18 contact surfaces, and prevent insanitary conditions at Defendants' Facilities, and shall address,
19 but not be limited to, contamination by chemical hazards and environmental pathogens; and

20 (2) Ensure that Defendants adhere to the Act, the Current Good Manufacturing
21 Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food Rule ("Food
22 CGMP & PC Rule"), 21 C.F.R. Part 117, and the Processing and Bottling of Bottled Drinking
23 Water Rule ("Bottled Water CGMP Rule"), 21 C.F.R. Part 129; and

24 (3) Conduct a hazard analysis of all foods manufactured by Defendants and
25 develop, to FDA's satisfaction, a written Food Safety Plan identifying required preventive
26 controls for Defendants' Products and manufacturing processes consistent with the Food CGMP
27 & PC Rule and the Bottled Water CGMP Rule, and establishing adequate measures to control for
28 all hazards requiring preventive controls consistent with 21 C.F.R. Part 117 Subpart C and

1 associated subparts; and

2 (4) Develop, to FDA's satisfaction, a written employee training program (in English
3 and any other language necessary to convey the substance of the training), addressing the Food
4 CGMP & PC Rule, the Bottled Water CGMP Rule, the Sanitation Plan, the Bottling Plan, and
5 the Food Safety Plan approved by FDA under paragraph 9(C), and after receiving FDA's
6 approval of such program in accordance with paragraph 9(C), train Defendants and their officers,
7 employees, and all other persons who perform duties at Defendants' Facilities in accordance with
8 such program, which shall include, but not be limited to, maintaining sanitation, conducting
9 adequate sampling and analysis, avoiding microbial contamination, and controlling chemical
10 hazards and environmental pathogens; and(5) Submit to FDA documentation demonstrating that
11 the Food Safety & PC Expert has adequately trained Defendants and their officers, employees,
12 and all other persons who perform duties at Defendants' Facilities; and

13 C. FDA has approved, in writing, the Sanitation Plan, Bottling Plan, Food Safety
14 Plan, and employee training program developed by the Expert, as specified in paragraph 9(B);
15 and

16 D. Defendants:

17 (1) Assign continuing responsibility for implementing and monitoring the
18 Sanitation Plan and the Bottling Plan to a person(s) who is trained in processing and bottled
19 drinking water requirements, see 21 C.F.R. Part 129, and who, by reason of background,
20 education, training, or experience, is qualified to maintain Defendants' Facilities in a sanitary
21 condition, coordinate and implement any necessary corrective actions, and who meets the
22 requirements of a PCQI as defined in 21 C.F.R. §117.3, and Defendants provide such person
23 with the authority and resources to achieve any necessary corrective action; and

24 (2) Ensure that the FDA-approved Sanitation Plan, Bottling Plan and Food Safety
25 Plan are available and accessible (in English and any other language necessary to convey the
26 substance of such documents) to their officers, employees, and all other persons who perform
27 duties at Defendants' Facilities; and

28 (3) Successfully complete the FDA-approved employee training program; and

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