BRIANNA GARDNER
SARAH WILLIAMS
Trial Attorneys
Consumer Protection Branch
U.S. Department of Justice, Civil Division
PO Box 386
Washington, DC 20044-0386
202-532-4786 (Gardner)
202-616-4269 (Williams)
Fax: 202-514-8742
Brianna.m.gardner@usdoj.gov
sarah.williams@usdoj.gov

Counsel for Plaintiff

UNITED STATES DISTRICT COURT
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-JAD-BNW **CONSENT DECREE OF PERMANENT INJUNCTION** ECF No. 3

Plaintiff, the United States of America, on behalf of the United States Food and Drug Administration ("FDA"), by its undersigned attorneys, having filed a Complaint for Injunction ("Complaint") against Affinitylifestyles.com, Inc., and Real Water, Inc., corporations; and Brent A. Jones and Blain K. Jones, individuals (collectively, "Defendants"), and Defendants having 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. This Court has jurisdiction over the subject matter and all parties to this action.

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

3. Defendants violated 21 U.S.C. § 331(uu), by operating a facility that manufactured, processed, packed, or held 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.

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

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

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

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

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

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

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

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

9. Upon entry of this Decree, 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 (including individuals, partnerships, corporations, subsidiaries, affiliates, and "doing business as" entities) (collectively, "Associated Persons") who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, processing, preparing, bottling, packing, labeling, holding, and/or distributing articles of food at or from Defendants' Facilities unless and until:

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

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

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

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

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

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

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

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

associated subparts; and

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

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

D. Defendants:

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

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

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

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