UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA, Plaintiff, v. VALLEY PROCESSING, INC., a corporation, and MARY ANN BLIESNER, individually, Defendants.	Civil Action No. 1:20-cv-3191-SAB **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Valley Processing, Inc. ("Valley

Processing") and Mary Ann Bliesner, (collectively, "Defendants"), and Defendants having appeared and consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest 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 that:

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

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

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or the causing thereof, articles of food within the meaning of 21 U.S.C. § 321(f), namely single strength fruit juice and fruit juice concentrate, including bulk apple, pear, and grape juice products ("juice products") that are adulterated, in violation of 21 U.S.C. § 331(a).

4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration of articles of food while such articles are held for sale after shipment of one or more components in interstate commerce.

5. The articles of food are 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 rendered injurious to health.

6. The articles of food are also adulterated within the meaning of 21 U.S.C. § 342(a)(3) in that the food "consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food."

7. Defendants represent to the Court that, with the exception of holding and shipping product for destruction pursuant to paragraph 9, at the time of entry of this Decree, they are not engaged in processing, manufacturing, preparing, packing, holding, or distributing any type of food. With the exception of any product in Defendant's possession that is covered by paragraph 9, if Defendants later intend to resume processing, manufacturing, preparing, packing, holding, or distributing food, they must first notify the United States Food and Drug Administration ("FDA") in writing at least ninety (90) calendar days in advance of resuming operations and comply with Paragraph 8 of this Decree. This notice shall identify the type(s) of food Defendants intend to receive, prepare, process, pack, hold, or distribute. Defendants shall not resume operations until FDA has inspected the Defendants' facility(ies) and operations pursuant to Paragraph 8(B)(xiv), Defendants have paid the costs of such inspection(s) pursuant to Paragraph 12, and Defendants have received written notice from FDA, as required by Paragraph 8(B)(xv), and then shall resume operations only to the extent authorized in FDA's written notice.

8. Upon entry of this Decree, 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 (including individuals,

directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, processing, manufacturing, preparing, packing, holding, and/or distributing, at or from any facility from which Defendants receive, prepare, process, manufacture, pack, hold, and/or distribute food ("Defendants' facilities"), any article of food, unless and until the following occur:

A. Defendants select an expert or experts (the "sanitation expert") having no personal or financial ties (other than a consulting agreement) to the Defendants or the Defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a written sanitation control program, covering the Defendants' manufacturing processes, cleaning and sanitizing operations, pest control, employee health and hygiene precautions, and plant construction and maintenance (including the plant's buildings and sanitation-related systems (plumbing, sewage disposal), equipment, and utensils contained therein), to protect against contamination of food, food-contact surfaces, and food-packaging materials with chemicals, toxins, microorganisms, and filth;

i. Defendants inform FDA in writing of the name and qualifications of the sanitation expert(s) as soon as they retain such expert. The sanitation expert(s) develops a written sanitation control program for preparing, packing, holding, and distributing the Defendants' juice products;

ii. FDA approves, in writing, the sanitation control program developed by the sanitation expert(s);

iii. Defendants make English and Spanish versions of the sanitation control program available and accessible to all their employees;

iv. Defendants develop a written employee training program (in English and Spanish) that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and the Defendants document that each employee has received such training;

v. Defendants assign the responsibility and authority for implementing and monitoring the sanitation control program on a continuing basis to an employee who is trained in sanitation control requirements;

vi. The sanitation expert(s) inspects the Defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein to determine whether the Defendants have adequately established and implemented the FDA-approved sanitation control program, whether Defendants have adequately addressed the FDA investigators' inspectional observations listed on each Form FDA-483 issued to the Defendants since 2016, and whether Defendants comply with Current Good Manufacturing Practice ("CGMP") requirements set forth in 21 C.F.R. Part 117 subparts A, B, and F; and

vii. The sanitation expert certifies in writing to FDA that Defendants: (a) have adequately established and implemented the FDA-approved sanitation control

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