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

program; (b) have adequately addressed FDA investigators' inspectional observations listed on each Form FDA-483 issued to the Defendants since 2016; and (c) comply with the CGMP requirements in 21 C.F.R. Part 117 subparts A, B, and F.

B. Defendants retain, at Defendants' expense, an independent person or persons ("expert"), who by reason of background, education, training, and experience, is qualified to develop and implement a Hazard Analysis Critical Control Point ("HACCP") plan for juice. The expert shall be without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families.

i. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity of the expert as soon as they retain such expert;

ii. The expert develops written HACCP plans for each type of juice processed by Defendants, consistent with 21 C.F.R. § 120.8(a)-(c);

iii. FDA has approved, in writing, the HACCP plan developed by the expert;

iv. Defendants establish and implement to FDA's satisfaction the written HACCP plan, developed by the expert and approved in writing by FDA, that is adequate to control food safety hazards likely to occur in juice processing, as required by 21 C.F.R. §§ 120.7 and 120.8;

v. Defendants perform a root cause analysis to determine sources of patulin and arsenic;

vi. Defendants have the expert validate and certify in writing to FDA that the control measures in Defendants' HACCP plan for apple and pear products are adequate to consistently control patulin;

vii. Defendants have the expert validate and certify in writing to FDA that the control measures in Defendants' HACCP plan for apple products are adequate to consistently control arsenic;

viii. The expert develops storage and traceability procedures for all food commodities, including grape juice concentrate;

ix. Defendants disclose to each customer in writing that receives any shipment as of or after the date of this Decree, all lots of juice product that has been blended into any distributed lot are within the expiration date of the final distributed lot;

x. FDA has inspected Defendants' facilities, including all records relating to the receipt, processing, manufacturing, preparation, packing, holding, and distribution of juice; and

xi. FDA has notified Defendants, in writing, that the processes and controls used for the receipt, processing, manufacturing, preparation, packing, holding, and distribution of food appear to be in compliance with all of the requirements specified in Paragraph 8 of this Decree, the Act, 21 C.F.R. Part 117 subparts A, B, and F, and 21 C.F.R. Part 120. And, if such notification is based upon one or more FDA inspections, Defendants have paid for such inspection(s) and other work at the rates specified in Paragraph 12.

9. Within ten (10) days of the entry of this Decree, Defendants shall provide to FDA an inventory of all remaining juice product, which will be stored at the facility at 130 US Grape Road, Sunnyside, WA 98944 until it is destroyed. Within two hundred seventy (270) days of the entry of this Decree, all juice product that is in the Defendants' possession at the time this Decree is signed by the parties shall be destroyed by the Defendants, at their own cost. Defendants shall provide FDA, every thirty (30) days from the date of entry of the Decree until the end of the two hundred seventy (270) day period, photographic evidence of Defendants' efforts to ship product for destruction, and a destruction report, consisting of certificates of destruction from the facility the Defendants use to dispose of the product, detailed with the quantity and lot numbers of barrels destroyed. If Defendants cannot ship any barrels of juice product for destruction within a particular thirty day period due to weather conditions or unavailability of a composter or landfill, Defendants must submit a letter to FDA detailing the reason(s) that they could not ship any product for destruction during that time period.

10. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material; to take photographs and make video recordings; to take samples of Defendants' raw

ingredients, in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, manufacturing, packing, holding, and/or distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. Defendants shall immediately provide any information or records to FDA, upon request, regarding the receipt, preparation, processing, manufacturing, packing, holding, or distribution of juice. Defendants shall maintain a copy of their HACCP plan and all records required by their HACCP plan and 21 C.F.R. Part 120 at the facility in a location where they are readily available for reference and inspection by FDA representatives. All records required to be kept by the HACCP plan and by regulation shall be retained for at least three (3) years after the date they are prepared and shall be presented immediately to FDA investigators upon request.

12. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $101.00 per hour and fraction thereof per representative for inspection work; $121.06 per hour or fraction thereof per representative for analytical or review work; $.575 per mile for travel by automobile; government rate or the equivalent for travel by

air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

13. 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 have received notice of this Decree, are permanently restrained and enjoined pursuant to the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

a. violates the Act, 21 U.S.C. § 33l(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) or 21 U.S.C. § 342(a)(3);

b. violates the Act, 21 U.S.C. § 331(k) by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) or 21 U.S.C. § 342(a)(3), while such articles are held for sale after shipment of one or more components in interstate commerce; and/or

c. results in the failure to implement and continuously maintain the requirements of this Decree.

14. If, at any time after entry of this Decree, FDA determines, based on the results

of an inspection, sample analysis, a report or data submitted by Defendants or the expert(s), or any other information, that Defendants have failed to comply with any provision of this Decree, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate action immediately, including, but not limited to, one or more of the following:

a. Cease receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any articles of food, until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations, and that Defendants may resume operations;

b. Recall all articles of food that have been distributed and/or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

c. Submit samples of raw ingredients, in-process or finished articles of food, containers, and/or packaging materials to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, and/or filth; and/or

d. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and its implementing regulations, including, but not limited to, requiring that Defendants re-implement or re-institute any of the requirements of this Decree.

15. The provisions of Paragraph 14 shall be apart from, and in addition to, all

other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 12 of this Decree.

16. Upon receipt of an FDA order described in Paragraph 14, Defendants shall immediately and fully comply with the terms of the order, and shall continue to comply with such terms, until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. After a cessation of operations , and while determining whether Defendants are in compliance with this Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

17. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America liquidated damages in the sum of two thousand dollars ($2000.00) for each violation of this Decree, the Act, and/or its implement regulations; an additional sum of two hundred fifty dollars ($250.00) for each day that the Defendants fail to comply with this Decree, the Act, and/or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also

be the basis for payment of the liquidated damages.

18. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to contempt proceedings.

19. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

20. Within ten (10) calendar days after entry of this Decree, Defendants shall:

a. provide a copy of this Decree by personal service or certified mail (restricted delivery, return receipt requested), to 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);

b. prominently post a copy of this Decree in an employee common area at

Defendants' facilities, and ensure that this Decree remains posted so long as it remains in effect; and

c. hold a meeting for their employees, at which Defendants shall describe the terms and obligations of this Decree.

Within twenty (20) calendar days after entry of this Decree, Defendants shall provide FDA with an affidavit of compliance with this Paragraph, stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

21. In the event that any Defendant becomes associated with any additional directors, officers, agents, representative, employees, attorneys, successors, assigns, or any additional persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) that are engaged in processing, manufacturing, preparing, packing, holding, and/or distributing food at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) calendar days after each instance that Defendant becomes associated with any individual persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this Paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this Paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate

Defendants' compliance with this Paragraph, Defendants shall provide such information or documentation to FDA.

22. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this Paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

23. Defendants shall address all communications required under this Decree to the HAFW6 /Seattle District Office 22215 26th Avenue SE, Suite 210, Bothell, Washington, with a copy to orahafwest6firmresponses@fda.hhs.gov. Defendants shall prominently mark the envelope, and the email copy, as "DECREE CORRESPONDENCE," and shall reference this civil action by case name and civil action number.

24. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED this 14th day of January, 2021.

United States District Judge

We hereby consent to the entry of the forgoing Decree:

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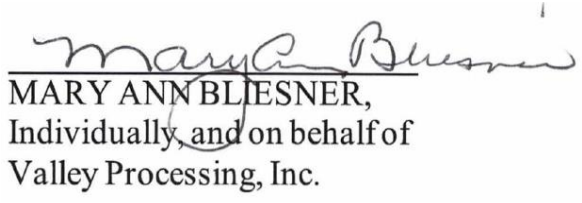

MARY ANN BLIESNER,
Individually, and on behalf of
Valley Processing, Inc.

LILLIAN HARDY
Attorney for Defendants
Mary Ann Bliesner and Valley
Processing, Inc.