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FILED IN THE
U.S. DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

Jan 14, 2021

SEAN F. McAVOY, CLERK

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

1 Processing”) and Mary Ann Bliesner, (collectively, “Defendants”), and Defendants
2 having appeared and consented to the entry of this Consent Decree of Permanent
3 Injunction (“Decree”) without contest and before any testimony has been taken, and the
4 United States of America having consented to this Decree;
5

6 **IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:**

7
8 1. This Court has jurisdiction over the subject matter and over all parties to this
9 action.

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11 2. The Complaint for Permanent Injunction states a cause of action against
12 Defendants under the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. §§
13 301 *et seq.*

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15 3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for
16 introduction into interstate commerce, or the causing thereof, articles of food within the
17 meaning of 21 U.S.C. § 321(f), namely single strength fruit juice and fruit juice
18 concentrate, including bulk apple, pear, and grape juice products (“juice products”) that
19 are adulterated, in violation of 21 U.S.C. § 331(a).
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22 4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration of
23 articles of food while such articles are held for sale after shipment of one or more
24 components in interstate commerce.

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26 5. The articles of food are adulterated within the meaning of 21 U.S.C. §
27 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions
28 whereby they may have become contaminated with filth or rendered injurious to health.

1 6. The articles of food are also adulterated within the meaning of 21 U.S.C. §
2 342(a)(3) in that the food “consists in whole or in part of any filthy, putrid, or
3 decomposed substance, or if it is otherwise unfit for food.”
4

5 7. Defendants represent to the Court that, with the exception of holding and
6 shipping product for destruction pursuant to paragraph 9, at the time of entry of this
7 Decree, they are not engaged in processing, manufacturing, preparing, packing, holding,
8 or distributing any type of food. With the exception of any product in Defendant’s
9 possession that is covered by paragraph 9, if Defendants later intend to resume
10 processing, manufacturing, preparing, packing, holding, or distributing food, they must
11 first notify the United States Food and Drug Administration (“FDA”) in writing at least
12 ninety (90) calendar days in advance of resuming operations and comply with Paragraph
13 8 of this Decree. This notice shall identify the type(s) of food Defendants intend to
14 receive, prepare, process, pack, hold, or distribute. Defendants shall not resume
15 operations until FDA has inspected the Defendants’ facility(ies) and operations pursuant
16 to Paragraph 8(B)(xiv), Defendants have paid the costs of such inspection(s) pursuant to
17 Paragraph 12, and Defendants have received written notice from FDA, as required by
18 Paragraph 8(B)(xv), and then shall resume operations only to the extent authorized in
19 FDA’s written notice.
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25 8. Upon entry of this Decree, Defendants and each and all of their directors,
26 officers, agents, representatives, employees, attorneys, successors, assigns, and any and
27 all persons in active concert or participation with any of them (including individuals,
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1 directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of
2 this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the
3 inherent equitable authority of this Court, from directly or indirectly receiving,
4 processing, manufacturing, preparing, packing, holding, and/or distributing, at or from
5 any facility from which Defendants receive, prepare, process, manufacture, pack, hold,
6 and/or distribute food (“Defendants’ facilities”), any article of food, unless and until the
7 following occur:
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10 A. Defendants select an expert or experts (the “sanitation expert”) having no
11 personal or financial ties (other than a consulting agreement) to the Defendants or the
12 Defendants’ manufacturing operations and who, by reason of background, education,
13 training, and experience, is qualified to develop, and ensure adequate implementation of,
14 a written sanitation control program, covering the Defendants’ manufacturing processes,
15 cleaning and sanitizing operations, pest control, employee health and hygiene
16 precautions, and plant construction and maintenance (including the plant’s buildings and
17 sanitation-related systems (plumbing, sewage disposal), equipment, and utensils
18 contained therein), to protect against contamination of food, food-contact surfaces, and
19 food-packaging materials with chemicals, toxins, microorganisms, and filth;
20
21

22 i. Defendants inform FDA in writing of the name and qualifications of
23 the sanitation expert(s) as soon as they retain such expert. The sanitation expert(s)
24 develops a written sanitation control program for preparing, packing, holding, and
25 distributing the Defendants’ juice products;
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1 ii. FDA approves, in writing, the sanitation control program developed
2 by the sanitation expert(s);

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

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

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

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

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

1 program; (b) have adequately addressed FDA investigators’ inspectional observations
2 listed on each Form FDA-483 issued to the Defendants since 2016; and (c) comply with
3 the CGMP requirements in 21 C.F.R. Part 117 subparts A, B, and F.
4

5 B. Defendants retain, at Defendants’ expense, an independent person or
6 persons (“expert”), who by reason of background, education, training, and experience, is
7 qualified to develop and implement a Hazard Analysis Critical Control Point (“HACCP”)
8 plan for juice. The expert shall be without personal or financial ties (other than the
9 consulting agreement between the parties) to Defendants or their immediate families.
10

11 i. Defendants shall notify the United States Food and Drug
12 Administration (“FDA”) in writing of the identity of the expert as soon as they retain
13 such expert;
14

15 ii. The expert develops written HACCP plans for each type of juice
16 processed by Defendants, consistent with 21 C.F.R. § 120.8(a)-(c);
17

18 iii. FDA has approved, in writing, the HACCP plan developed by the
19 expert;
20

21 iv. Defendants establish and implement to FDA’s satisfaction the written
22 HACCP plan, developed by the expert and approved in writing by FDA, that is adequate
23 to control food safety hazards likely to occur in juice processing, as required by 21 C.F.R.
24 §§ 120.7 and 120.8;
25

26 v. Defendants perform a root cause analysis to determine sources of
27 patulin and arsenic;
28

1 vi. Defendants have the expert validate and certify in writing to FDA that
2 the control measures in Defendants' HACCP plan for apple and pear products are
3 adequate to consistently control patulin;
4

5 vii. Defendants have the expert validate and certify in writing to FDA that
6 the control measures in Defendants' HACCP plan for apple products are adequate to
7 consistently control arsenic;
8

9 viii. The expert develops storage and traceability procedures for all food
10 commodities, including grape juice concentrate;
11

12 ix. Defendants disclose to each customer in writing that receives any
13 shipment as of or after the date of this Decree, all lots of juice product that has been
14 blended into any distributed lot are within the expiration date of the final distributed lot;
15

16 x. FDA has inspected Defendants' facilities, including all records
17 relating to the receipt, processing, manufacturing, preparation, packing, holding, and
18 distribution of juice; and
19

20 xi. FDA has notified Defendants, in writing, that the processes and
21 controls used for the receipt, processing, manufacturing, preparation, packing, holding,
22 and distribution of food appear to be in compliance with all of the requirements specified
23 in Paragraph 8 of this Decree, the Act, 21 C.F.R. Part 117 subparts A, B, and F, and 21
24 C.F.R. Part 120. And, if such notification is based upon one or more FDA inspections,
25 Defendants have paid for such inspection(s) and other work at the rates specified in
26 Paragraph 12.
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1 9. Within ten (10) days of the entry of this Decree, Defendants shall provide to
2 FDA an inventory of all remaining juice product, which will be stored at the facility at
3 130 US Grape Road, Sunnyside, WA 98944 until it is destroyed. Within two hundred
4 seventy (270) days of the entry of this Decree, all juice product that is in the Defendants'
5 possession at the time this Decree is signed by the parties shall be destroyed by the
6 Defendants, at their own cost. Defendants shall provide FDA, every thirty (30) days from
7 the date of entry of the Decree until the end of the two hundred seventy (270) day period,
8 photographic evidence of Defendants' efforts to ship product for destruction, and a
9 destruction report, consisting of certificates of destruction from the facility the
10 Defendants use to dispose of the product, detailed with the quantity and lot numbers of
11 barrels destroyed. If Defendants cannot ship any barrels of juice product for destruction
12 within a particular thirty day period due to weather conditions or unavailability of a
13 composter or landfill, Defendants must submit a letter to FDA detailing the reason(s) that
14 they could not ship any product for destruction during that time period.
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20 10. FDA shall be permitted, without prior notice and as and when FDA deems
21 necessary, to make inspections of Defendants' facilities and, without prior notice, take
22 any other measures necessary to monitor and ensure continuing compliance with the
23 terms of this Decree, the Act, and its implementing regulations. During the inspections,
24 FDA shall be permitted to have immediate access to buildings, equipment, raw
25 ingredients, in-process and finished articles of food, containers, and packaging material;
26 to take photographs and make video recordings; to take samples of Defendants' raw
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1 air or other means; and the published government per diem rate or the equivalent for the
2 areas in which the inspections are performed per representative and per day for
3 subsistence expenses, where necessary. In the event that the standard rates applicable to
4 FDA supervision of court-ordered compliance are modified, these rates shall be increased
5 or decreased without further order of the Court.
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8 13. Defendants and each and all of their directors, officers, agents,
9 representatives, employees, attorneys, successors, assigns, and any and all persons in
10 active concert or participation with any of them (including individuals, directors,
11 partnerships, corporations, subsidiaries, and affiliates) who have received notice of this
12 Decree, are permanently restrained and enjoined pursuant to the provisions of 21 U.S.C.
13 § 332(a) from directly or indirectly doing or causing any act that:
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16 a. violates the Act, 21 U.S.C. § 331(a), by introducing, or delivering for
17 introduction, into interstate commerce, articles of food that are adulterated within the
18 meaning of 21 U.S.C. § 342(a)(4) or 21 U.S.C. § 342(a)(3);
19

20 b. violates the Act, 21 U.S.C. § 331(k) by causing articles of food to be
21 adulterated within the meaning of 21 U.S.C. § 342(a)(4) or 21 U.S.C. § 342(a)(3), while
22 such articles are held for sale after shipment of one or more components in interstate
23 commerce; and/or
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25 c. results in the failure to implement and continuously maintain the
26 requirements of this Decree.
27

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

1 of an inspection, sample analysis, a report or data submitted by Defendants or the
2 expert(s), or any other information, that Defendants have failed to comply with any
3 provision of this Decree, the Act, or its implementing regulations, or that additional
4 corrective actions are necessary to achieve compliance with this Decree, the Act, or its
5 implementing regulations, FDA may, as and when it deems necessary, notify Defendants
6 in writing of the noncompliance and order Defendants to take appropriate action
7 immediately, including, but not limited to, one or more of the following:
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10 a. Cease receiving, processing, manufacturing, preparing, packing, holding,
11 and/or distributing any articles of food, until Defendants receive written notification from
12 FDA that Defendants appear to be in compliance with the Decree, the Act, and its
13 implementing regulations, and that Defendants may resume operations;
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16 b. Recall all articles of food that have been distributed and/or are under the
17 custody and control of Defendants' agents, distributors, customers, or consumers;
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19 c. Submit samples of raw ingredients, in-process or finished articles of food,
20 containers, and/or packaging materials to a qualified laboratory to determine whether
21 they are contaminated with chemicals, toxins, microorganisms, and/or filth; and/or
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23 d. Take any other corrective actions as FDA deems necessary to protect the
24 public health or bring Defendants into compliance with this Decree, the Act, and its
25 implementing regulations, including, but not limited to, requiring that Defendants re-
26 implement or re-institute any of the requirements of this Decree.
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28 15. The provisions of Paragraph 14 shall be apart from, and in addition to, all

1 other remedies available to FDA. Defendants shall pay all costs of recalls and other
2 corrective actions, including the costs of FDA's supervision, inspections, investigations,
3 analyses, examinations, and reviews to implement and monitor recalls and other
4 corrective actions, at the rates specified in Paragraph 12 of this Decree.
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6 16. Upon receipt of an FDA order described in Paragraph 14, Defendants shall
7 immediately and fully comply with the terms of the order, and shall continue to comply
8 with such terms, until Defendants receive written notification from FDA that Defendants
9 appear to be in compliance with this Decree, the Act, and its implementing regulations.
10 After a cessation of operations, and while determining whether Defendants are in
11 compliance with this Decree, the Act, and its implementing regulations, FDA may
12 require Defendants to re-institute or re-implement any of the requirements of this Decree.
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16 17. If any Defendant fails to comply with the provisions of this Decree, the Act,
17 and/or its implementing regulations, then Defendants shall pay to the United States of
18 America liquidated damages in the sum of two thousand dollars (\$2000.00) for each
19 violation of this Decree, the Act, and/or its implement regulations; an additional sum of
20 two hundred fifty dollars (\$250.00) for each day that the Defendants fail to comply with
21 this Decree, the Act, and/or its implementing regulations; and an additional sum equal to
22 twice the retail value of each shipment of adulterated food. Defendants understand and
23 agree that the liquidated damages specified in this Paragraph are not punitive in nature
24 and their imposition does not in any way limit the ability of the United States to seek, and
25 the Court to impose, additional criminal or civil penalties based on conduct that may also
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1 be the basis for payment of the liquidated damages.

2 18. If any Defendant violates this Decree and is found in civil or criminal
3 contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for
4 its attorneys' fees (including overhead), travel expenses incurred by attorneys and
5 witnesses, expert witness fees, administrative and court costs, investigation and analytical
6 expenses incurred in bringing the contempt action, and any other costs or fees related to
7 contempt proceedings.
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10 19. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be
11 final. All decisions conferred upon FDA in this Decree shall be vested in FDA's
12 discretion and, if contested, shall be reviewed by this Court under the arbitrary and
13 capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA
14 decision rendered pursuant to this Decree shall be based exclusively on the written record
15 before FDA at the time the decision was made. No discovery shall be taken by either
16 party.
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18 20. Within ten (10) calendar days after entry of this Decree, Defendants shall:
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20 a. provide a copy of this Decree by personal service or certified mail
21 (restricted delivery, return receipt requested), to each and all of their directors, officers,
22 agents, representatives, employees, attorneys, successors, assigns, and any and all persons
23 in active concert or participation with any of them (including individuals, directors,
24 partnerships, corporations, subsidiaries, and affiliates);
25

26 b. prominently post a copy of this Decree in an employee common area at
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1 Defendants' facilities, and ensure that this Decree remains posted so long as it remains in
2 effect; and

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

6
7 Within twenty (20) calendar days after entry of this Decree, Defendants shall
8 provide FDA with an affidavit of compliance with this Paragraph, stating the fact and
9 manner of compliance and identifying the names and positions of all persons so notified.

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

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4 22. Defendants shall notify FDA in writing at least fifteen (15) calendar days
5 before any change in ownership, name, or character of their business, including
6 reorganization, relocation, dissolution, assignment, or lease or sale of the business or any
7 assets of the business, such as buildings, equipment, or inventory, that may affect
8 compliance with the obligations arising from this Decree. Defendants shall provide any
9 prospective successor or assign with a copy of this Decree at least ten (10) calendar days
10 before the assignment or change in business, and shall provide FDA with an affidavit of
11 compliance with this Paragraph within ten (10) calendar days of providing a copy of this
12 Decree to a prospective successor or assign.
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16 23. Defendants shall address all communications required under this Decree to
17 the HAFW6/Seattle District Office 22215 26th Avenue SE, Suite 210, Bothell,
18 Washington, with a copy to orahafwest6firmresponses@fda.hhs.gov. Defendants shall
19 prominently mark the envelope, and the email copy, as "DECREE
20 CORRESPONDENCE," and shall reference this civil action by case name and civil
21 action number.
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24 24. This Court retains jurisdiction of this action for the purpose of enforcing or
25 modifying this Decree and for the purpose of granting such additional relief as may be
26 necessary or appropriate.
27

28 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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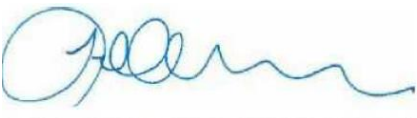
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FOR DEFENDANTS:



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



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