UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>BRAVO PACKING, INC., a corporation, and JOSEPH MEROLA and AMANDA LLOYD, individuals,<br><br>Defendants. | Civil Action No. 22-cv-1380-NLH-SAK<br>Hon. Noel L. Hillman<br>Hon. Sharon A. King |

**CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Injunction against Bravo Packing, Inc. ("Bravo") and Joseph Merola and Amanda Lloyd (collectively, "Defendants"), and Defendants having appeared and consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the Complaint, 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 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. The Complaint alleges 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 animal food within the meaning of 21 U.S.C. § 321(f), namely raw pet food products, that are adulterated.

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

5. The Complaint alleges articles of pet food are adulterated within the meaning of 21 U.S.C. § 342(a)(1) in that they bear or contain a poisonous or deleterious substance, namely *Salmonella,* which may render them injurious to health, and 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. Upon entry of this Decree, the Defendants and each and all of their agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive 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 receiving, processing, manufacturing, preparing, packing, holding, and/or distributing pet food, at or from their facility at 59 N. Golfwood Ave., Carneys Point, New Jersey and any other locations at which Defendants now or in the future receive, process, manufacture, prepare, pack, hold, or distribute articles of pet food, unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial ties (other than the retention agreement) to the Defendants or their families, which is qualified to collect finished raw pet food product and environmental samples from within the Defendants' facility and analyze those samples for the

presence of *Salmonella* and *Listeria monocytogenes* (*"L. mono"*), and other pathogenic microorganisms, in a method that is acceptable to the FDA. The Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain certain provisions, acceptable to FDA, for regular environmental and finished raw pet food product sample collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and the methods of analysis, in accordance with the Environmental Monitoring Program discussed in paragraph C below;

B. Defendants retain, at their expense, an independent expert(s) ("sanitation expert") having no personal or financial ties (other than the retention agreement) to the Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to inspect the Defendants' facility and to determine whether the methods, facilities, and controls are operated and administered in conformity with the Act and all applicable regulations. The Defendants shall notify FDA in writing of the name(s) and qualifications of the sanitation expert(s) as soon as they retain such expert(s);

C. Defendants' sanitation expert(s), in consultation with the laboratory, after review of all FDA observations cited on the List of Inspectional Observation ("Forms FDA 483") issued to the Defendants on May 28, 2021, April 7, 2021, and August 6, 2019, develop a written Environmental Monitoring Program, acceptable to FDA, which shall include, at a minimum, the following:

i. An effective written sanitation control program that establishes adequate methods, facilities, and controls for receiving, processing, manufacturing, preparing, packing, holding, and distributing pet foods to minimize the risk of introduction of *Salmonella*

into the Defendants' pet food and to ensure that the pet food is not adulterated, within the meaning of 21 U.S.C. § 342(a). Such methods, facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering the Defendants' facility and all equipment therein suitable for use in receiving, processing, manufacturing, preparing, packing, holding, and distributing articles of pet food to prevent the articles of pet food from becoming adulterated, and instituting procedures to ensure that the facility and equipment therein are continuously maintained in a sanitary condition;

ii. A written employee training program, in English and Spanish, that includes, at a minimum, instruction on the principles of pet food hygiene and pet food safety, including the importance of employee health and personal hygiene, sanitary pet food handling techniques, and documentation that each employee has received such training;

iii. An effective program of environmental monitoring and testing of the facility, conducted by the laboratory, to ensure that pathogenic microorganisms are not present within the facility, excluding the slaughter room. Environmental monitoring shall include, but not be limited to, collecting swab samples from pet food-contact surfaces, equipment, and other environmental sites throughout the facility (where the raw ingredients, in-process, and finished pet food products are received, processed, manufactured, prepared, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analysis of collected samples, in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph 6.C.iii are sent to FDA within two (2) business days of receipt by the Defendants;

iv. A plan for remedial action should *Salmonella*, *L. mono,* or any other pathogenic microorganism be detected; and

v. Assigning continuing responsibility for the operation of the Environmental Monitoring Program to a person or persons who, by reason of background, experience, or education, is qualified to maintain the facility in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and providing such person with the authority and resources to achieve the necessary corrections.

D. The sanitation expert(s) conducts a comprehensive inspection of the Defendants' facility and the methods and controls used to receive, process, manufacture, prepare, pack, hold, and distribute pet foods to determine whether the Defendants have adequately established and implemented all necessary changes and are operating in compliance with this Decree, the Act, and the Current Good Manufacturing Practice ("CGMP") requirements set forth in 21 C.F.R. Part 507. Defendants shall ensure that the expert(s) shall submit their findings from this inspection to the Defendants and FDA concurrently, within ten (10) business days of completion of the inspection;

E. The sanitation expert certifies in writing to FDA that Defendants: (a) have adequately established and implemented the FDA-approved Environmental Monitoring Program pursuant to paragraph 6.C.iii; (b) have adequately addressed FDA investigators' inspectional observations listed on each Form FDA-483 issued to the Defendants since 2019; and (c) comply with the CGMP requirements in 21 C.F.R. Part 507 including:

i. Documentation that they have cleaned and sanitized their facility and have received laboratory results showing that *Salmonella*, *L .mono,* and other pathogenic microorganisms are no longer present in the facility;

ii. Specific measures that they have taken to address each of the violations documented by FDA; and

iii. A copy of the Environmental Monitoring Program;

F. Defendants shall destroy, under FDA supervision, all in-process and finished articles of pet food currently in their custody, control, or possession.

G. Defendants recall, to the retail level and at their own expense, all pet food distributed since May 25, 2021, or Defendants provide documentation, to FDA's satisfaction, showing that all products distributed since May 25, 2021 have been removed from the market.

H. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, conducts inspections of the Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of pet food, and relevant records contained therein;

I. FDA notifies the Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs 6 (A)-(H) of this Decree, the Act, and the CGMP regulations at 21 C.F.R. Part 507;

J. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to paragraph 10, at the rates set forth in paragraph 14 below.

7. Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under 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. §331(a), by introducing, or delivering for introduction, into interstate commerce articles of pet food that are adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of pet food to be adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) or (a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce; or

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

8. Upon resuming operations after completing the requirements of paragraph 6, the Defendants shall continuously implement the following steps to prevent further *Salmonella*, *L. mono,* and other pathogenic microorganism contamination of their pet food products and facility:

A. Effectively implement, on an ongoing basis, the Environmental Monitoring Program developed pursuant to paragraph 6(C), unless the Defendants submit, and FDA approves in writing, an alternative environmental monitoring program, consisting of validated methods and controls that are shown to FDA's satisfaction to eliminate *Salmonella*, *L. mono,* and other pathogenic microorganisms in pet food. If in the event that the Defendants, the sanitation expert(s), or laboratory, determines that the Environmental Monitoring Program needs to be revised, the Defendants shall provide suggested changes to FDA in writing at least twenty (20) days prior to their implementation for the first three years after resuming pet food operations. After the first three years following resumption of pet food operations, Defendants shall maintain records of any modifications to the Environmental Monitoring Program that will be made available to FDA upon request.

B. Conduct finished product testing in the following manner:

i. Immediately upon resumption of operations after the completion of the requirements of paragraph 6 (A)-(H), the Defendants shall test for *Salmonella*, *L. mono,* and speciate if isolated, in all lots of each finished pet food product for at least five consecutive production days using a sampling and testing method acceptable to FDA;

ii. After the adequate completion of sampling and testing under the previous paragraph, the Defendants shall test at least one lot of each finished pet food product per day for the next twenty (20) production days;

iii. After the adequate completion of sampling and testing under the previous subparagraph ii, the Defendants shall test at least one lot of each finished pet food product per every five (5) production days for the next three (3) months; and

iv. After the adequate completion of sampling and testing under the previous paragraph, the Defendants shall test at least one lot of each finished pet food product per quarter thereafter.

C. If any laboratory test completed pursuant to sub-paragraphs 8(B)(i)-(iii) shows the presence of *Salmonella*, *L. mono*, or other pathogenic microorganisms in finished pet food product, then the Defendants must immediately cease production and distribution of all pet food until they have determined and corrected the cause of the microbial contamination and take the following steps:

i. The Defendants shall notify the FDA within two (2) business days of receiving a laboratory report of a presumptive positive test result;

ii. Finished products found to contain *Salmonella*, *L. mono*, or other pathogenic microorganisms cannot be reconditioned and resold as finished raw pet food. Such contaminated products shall be either be destroyed after FDA notification or directed to a process

that will inactivate the pathogens (e.g., rendering). Defendants must submit a written plan for any process that will inactivate pathogens to FDA and receive written approval of the plan from FDA before beginning the process;

iii. Any environmental samples or pet food products found to be positive for *Salmonella*, *L. mono*, or other pathogenic microorganisms through laboratory analysis shall be made available to the FDA, upon request, for further analysis;

iv. Once the cause of the contamination has been corrected, the Defendants shall reinstate the complete sequence of testing under paragraph 8 anew.

9. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analysis pursuant to paragraph 6(A), Defendants terminate or alter their service contract with the laboratory in any way, Defendants shall notify FDA within five (5) business days. Defendants shall contract with a new laboratory for collection and analysis services promptly, and Defendants shall provide a copy of the new service contract to FDA within five (5) business days of execution.

10. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility 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, processing, manufacturing, preparing, 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, packing, holding, or distribution of pet food. Defendants shall maintain a copy of all records required by 21 C.F.R. Part 507 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 21 C.F.R. Part 507 shall be retained for at least two (2) years after the date they are prepared and shall be presented immediately to FDA investigators upon request.

12. If, at any time after this entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, report or data prepared or submitted by Defendants or the sanitation expert, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its applicable regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease preparing, manufacturing, processing, packing, holding, and/or distributing any and all articles of animal food;

B. Recall, at Defendants' expense, any and all articles of animal food that have been distributed and/or are under the custody and control of Defendants' agents,

distributors, customers, or consumers that in FDA's judgment is adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Submit samples to a qualified laboratory for analysis;

F. Institute or reimplement any of the requirements set forth in this Decree;

G. Issue a safety alert; and/or

H. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

13. Upon receipt of any order issued by FDA pursuant to paragraph 12, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 12 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, investigations, supervision, examinations, sampling, testing, travel time, and subsistence expenses to implement and monitor the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in paragraph 14.

14. 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: $102.39 per hour or fraction thereof per representative for inspection and investigative work; $122.71 per hour or fraction thereof per representative for analytical or review work; $0.56 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate 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.

15. 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.

16. 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.

17. 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' facility 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, provided Defendant has employees that are receiving, preparing, manufacturing, processing, packing, holding, and/or distributing pet food; at the time of entry of this Decree.

18. Within twenty (20) calendar days after entry of this Decree, Defendants shall provide FDA with an affidavit of compliance with paragraph 17, stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

19. After entry of this Decree, 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 manufacturing, processing, preparing, packing, holding, 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.

20. 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.

21. Defendants shall address all communications required under this Decree to the Human & Animal Food Division II East, New Jersey District Office, 10 Waterview Boulevard, Parsippany, New Jersey 07054, with a copy to orahafeast2firmresponses@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.

22. The parties may at any time petition each other in writing to modify any deadline provided herein and if the parties mutually agree in writing to modify a deadline, such modification may be granted and may become effective without leave of the Court.

23. 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.

24. No sooner than five (5) years after entry of this Decree, Defendants may petition this Court for an order dissolving this Decree. If Defendants have maintained, to FDA's satisfaction, a state of compliance with this Decree, the Act, and all applicable regulations for five (5) years preceding Defendant's petition, the United States will not oppose such petition.

SO ORDERED this___ day of _____, 2022.

_____
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

FOR DEFENDANTS:

JOSEPH MEROLA
Individually and on behalf of BRAVO PACKING, INC.

AMANDA LLOYD
Individually and on behalf of BRAVO PACKING, INC.

JOHN G. DILLARD
Olsson Frank Weeda Terman Matz PC
2000 Pennsylvania Ave., NW
Suite 3000
Washington, DC 20006
202-789-1212
jdillard@ofwlaw.com
Attorney for Defendants

FOR PLAINTIFF:

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director
Consumer Protection Branch

ALLAN GORDUS
Assistant Director

NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
202-305-2428
noah.t.katzen@usdoj.gov

OF COUNSEL:

DANIEL J. BARRY
Acting General Counsel
Department of Health and Human Services

PERHAM GORJI
Deputy Chief Counsel for Litigation
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

TARA BOLAND
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
(301) 796-8549