UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

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