

Changing the World for Animals

July 21, 2021

Submitted via email

Jessica Weber, Compliance Officer Food and Drug Administration Office of Regulatory Affairs Baltimore District Office Human and Food Animal Division East II 6000 Metro Drive, Suite 101 Baltimore, Maryland 21215 jessica.weber@fda.hhs.gov

Loel Muetter, Program Manager New Jersey Department of Health Public Health and Food Protection Program P.O. Box 369 Trenton, New Jersey 08625-0369 loel.muetter@doh.nj.gov

Dear Ms. Weber and Mr. Muetter,

On behalf of Animal Outlook, I write again to inform you of recent incidents involving Bravo Packing, Inc. ("Bravo") in violations of both federal and state food safety laws. This correspondence follows our December 10, 2020 letter, in which we informed you of the presence of *Salmonella* on a sample of Bravo's Performance Dog Diet ("PDD") dog food. The incidents described herein represent the latest in a long, tortured history of food safety violations at Bravo. We respectfully renew our request that the Food and Drug Administration ("FDA") and New Jersey Department of Health ("NJDH") investigate and enforce both federal and state and laws to the fullest extent possible, including permanent termination of Bravo's operations.

As you are well aware from prior enforcement actions, Bravo is located at 59 Golfwood Avenue, Carney's Point, New Jersey 08069, and is operated by its president, Amanda Lloyd, and its secretary, Joseph Merola. The company produces and distributes dog food called Performance Dog Diet or Performance Dog ("PDD") through its subsidiary, Tefco, located in Brooklyn, New York.<sup>1</sup> Bravo also slaughters horses at the same facility to produce food for captive exotic animals.<sup>2</sup>

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<sup>&</sup>lt;sup>1</sup> *Performance Dog Diet*, TEFCO RAW DOG FOOD, http://www.rawdogfoodwholesale.com/performance-dog-diet/ (last visited June 23, 2021).

<sup>&</sup>lt;sup>2</sup> Home Page, BRAVO PACKING, INC., http://www.bravopacking.com/index.html (last visited June 23, 2021).

Despite the FDA's repeated warnings, recalls, and opportunities for compliance, Bravo continues to flout federal and state food safety laws, jeopardizing the health and safety of unsuspecting consumers and their animals. The FDA and the NJDH must intervene to permanently end Bravo's continued proliferation of dangerously tainted products.

## I. The Current Evidence of Food Safety Violations is Only the Most Recent in Bravo's Long, Disturbing History that Includes Numerous Recalls, Repeat Violations, and Repudiation of Food Safety Laws.

On June 1, 2021, Animal Outlook's investigator recorded video footage depicting Bravo<sup>4</sup> preparing carcasses for use as animal food and slaughtering a non-ambulatory cow in deplorable, insanitary conditions. Just feet from pools of blood, standing water, and mounds of feces in which the conscious, non-ambulatory cow lay, Bravo prepared a pair of carcasses for use as animal food in total disregard of the potential for contamination. Bravo then attached a chain to the cow and dragged her filthy, soiled body into the open door of the food preparation area and slaughtered her to use her carcass for animal food. By producing food in such squalid, insanitary conditions, Bravo violated federal and state law prohibiting the manufacture of "adulterated" food and must be punished by the FDA and the NJDH.

In the following image taken from the video, Bravo sprays water on an exposed carcass while a newly delivered cow—still conscious and coated in manure—lies mere feet away in puddles of blood, water, and feces.

<sup>&</sup>lt;sup>3</sup> Animal Outlook has separately contacted law enforcement authorities, including the United States Department of Agriculture, the New Jersey Department of Agriculture, and the Salem County Prosecutor's Office, regarding the animal cruelty depicted in the video.

<sup>&</sup>lt;sup>4</sup> As used in this memorandum, the term "Bravo" encompasses Bravo's employee, owners, and the corporation itself.



The image below depicts two carcasses hanging in the slaughter area just feet from the soiled and filthy concrete floor and the conscious cow.



The following image depicts the newly delivered cow being dragged by a chain into the slaughter area, trailing streaks of blood, water, and feces behind her.



This event is far from the first time Bravo has produced "adulterated" products. Bravo's history of food safety violations is well-documented and troubling:

- On August 4, 2016, following the collection of samples during an inspection, the FDA issued an untitled letter ("UTL") stating that Bravo had sold horse meat for exotic animal food that was dangerously "contaminated with Pentobarbital and Phenytoin."<sup>5</sup>
- Less than two years later, on June 22, 2018, the FDA received a consumer complaint alleging that Bravo's products are produced "from dead, dying, and disabled livestock," include the meat of horses euthanized using sodium pentobarbital, and that the company's marketing allegations regarding the use of beef obtained only from USDA-inspected plants were fraudulent.<sup>6</sup> In response to the consumer complaint, the FDA inspected Bravo on July 18, 2018.<sup>7</sup> On September 18, 2018, following testing conducted pursuant to that inspection, Bravo announced a recall of "all Performance Dog products" because of their "potential to be contaminated with *Salmonella*."<sup>8</sup>

<sup>&</sup>lt;sup>5</sup> FOOD AND DRUG ADMINISTRATION, Consumer Complaint/Injury Report, Complaint #153962, June 22, 2018. <sup>6</sup> *Ibid.* 

<sup>&</sup>lt;sup>7</sup> FOOD AND DRUG ADMINISTRATION, Establishment Inspection Report, FEI # 1000121624, July 18, 2018.

<sup>&</sup>lt;sup>8</sup> Bravo Packing, Inc. Recalls Performance Dog Raw Pet Food Because of Possible Salmonella Health Risk to Humans and Animals, FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bravo-packing-inc-recalls-performance-dog-raw-pet-food-because-possible-salmonella-health-risk (last visited June 23, 2021).

- The following summer, on July 22, July 24, and August 6, 2019, the FDA conducted an inspection at Bravo to follow up on compliance issues stemming from the September 18, 2018 recall.<sup>9</sup> During these inspections, the FDA collected a sample of PDD that subsequently tested positive for *Salmonella* and *Listeria monocytogenes*.<sup>10</sup> Accordingly, the FDA declared the raw pet foods manufactured at Bravo to be "adulterated"<sup>11</sup> and publicly cautioned pet owners on September 26, 2019 not to feed their pets any PDD and to throw the product away "in a secure container where other animals, including wildlife, cannot access it."<sup>12</sup> The FDA later issued a Warning Letter<sup>13</sup> summarizing the findings of its inspection and noting that the agency had found "significant violations of the Current Good Manufacturing Practice Hazard Analysis and Risk-Based Preventative Controls for Food for Animals."<sup>14</sup>
- In December 2020, Animal Outlook notified the FDA and the NJDH that a sample of PDD had tested positive for *Salmonella*. Subsequently, the FDA inspected Bravo and found samples of PDD contaminated with both *Salmonella* and *Listeria monocytogenes*, leading to Bravo's March 3, 2021 recall of all PDD and Ground Beef Raw Pet Food.<sup>15</sup> On March 16, 2021, Bravo expanded its recall to include "all pet food and bones in all package sizes" due to potential cross-contamination.<sup>16</sup>

For years, Bravo has flouted food safety rules and continued producing animal food in filthy, deplorable conditions despite repeated warnings and actions from the FDA. As demonstrated by Animal Outlook's recent video and laboratory test result, Bravo continues to operate with no regard for the safety and welfare of unsuspecting consumers and animals who buy, handle, or are fed its products. The FDA and NJDH owe these consumers and animals a duty to protect them from such dangerous conduct and should shutter Bravo for good to forcibly end Bravo's continued disregard for federal food safety laws.

<sup>12</sup> FDA Cautions Pet Owners Not to Feed Performance Dog Raw Pet Food Due to Salmonella, Listeria monocytogenes, FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/animal-veterinary/outbreaks-and-advisories/fda-cautions-pet-owners-not-feed-performance-dog-raw-pet-food-due-salmonella-listeria-monocytogenes#:~:text=The%20U.S.%20Food%20and%20Drug%20Administration%20is%20cautioning%20pet% 20owners,manufactured%20by%20Bravo%20Packing%2C%20Inc. (last visited June 23, 2021).

<sup>&</sup>lt;sup>9</sup> FOOD AND DRUG ADMINISTRATION, CMS #592718 Warning Letter, Mar. 16, 2020.

<sup>&</sup>lt;sup>10</sup> FDA Cautions Pet Owners Not to Feed Performance Dog Raw Pet Food Due to Salmonella, Listeria monocytogenes, FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/animal-veterinary/outbreaks-and-advisories/fda-cautions-pet-owners-not-feed-performance-dog-raw-pet-food-due-salmonella-listeria-monocytogenes#:~:text=The%20U.S.%20Food%20and%20Drug%20Administration%20is%20cautioning%20pet% 20owners,manufactured%20by%20Bravo%20Packing%2C%20Inc. (last visited June 23, 2021). <sup>11</sup> Ibid.

<sup>&</sup>lt;sup>13</sup> The March 16, 2020 FDA Warning Letter copied the New Jersey Department of Health, Public Health and Food Protection Program Manager, Loel Muetter.

<sup>&</sup>lt;sup>14</sup> FOOD AND DRUG ADMINISTRATION, CMS #592718 Warning Letter, Mar. 16, 2020.

<sup>&</sup>lt;sup>15</sup> Bravo Packing, Inc. Recalls All Performance Dog and Ground Beef Raw Pet Food Because of Possible Salmonella and Listeria Monocytogenes Health Risk to Humans and Animals, FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bravo-packing-inc-recalls-all-performance-dogand-ground-beef-raw-pet-food-because-possible (last visited June 23, 2021).

<sup>&</sup>lt;sup>16</sup> Bravo Packing, Inc. Expands Previously Announced Voluntary Recall of Pet Food Products Due to Potential Salmonella and Listeria monocytogenes Health Risks to Humans and Animals, FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bravo-packing-inc-expands-previously-announced-voluntary-recall-pet-food-products-due-potential (last visited June 23, 2021).

# II. Bravo's Preparation of Animal Food in Insanitary Conditions Violates the FDCA and the FDA Must Force It to Stop.

The federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act") prohibits a sweeping range of conduct, including the conditions documented at Bravo. Most relevant, 21 U.S.C. § 342(a)(4) states that "[a] food shall be deemed to be adulterated" under the Act "if it has been prepared, packed, or held under *insanitary conditions* whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."<sup>17</sup>

While the FDCA does not explicitly define "insanitary conditions," courts have repeatedly held that the term "should be construed to have its usual and ordinary meaning."<sup>18</sup> As defined by the Merriam-Webster Dictionary, the term "insanitary" means "unclean enough to endanger health,"<sup>19</sup> and the Oxford Dictionary defines the term similarly as "[s]o dirty or ridden with germs to be a danger to health."<sup>20</sup>

In addition to the "usual and ordinary meaning," the FDA's own guidance documents and warning letters further outline the contours of the term. These documents provide specific examples and descriptions of "insanitary conditions" and leave no doubt that the animal food produced at Bravo is "adulterated" and in contravention to the requirements of the FDCA.

- A. <u>The Presence of Fecal Matter and Standing Water in and Around Bravo's Slaughter Area</u> <u>Constitutes "Insanitary Conditions" under the FDCA and Renders the Product</u> <u>"Adulterated."</u>
  - 1. The presence of fecal matter near food production areas constitutes "insanitary conditions."

The presence of fecal matter is incompatible with the safe production of food, and the FDA has repeatedly decried its presence. Most relevant here, in a June 2020 Warning Letter to a pet food manufacturer, the FDA cited the facility in part because "[o]n the kill floor, while employees removed hides from three cow carcasses, stomach contents and fecal matter were observed spilling over onto exposed carcasses."<sup>21</sup>

In addition, in an October 2020 Warning Letter to a salad manufacturing facility, the FDA observed the risks of fecal matter seepage in a canal near the cabbage fields, stating that "water and soil contaminated with fecal matter may act as a vehicle of transmission for *C*. *cayetanensis* infection."<sup>22</sup>

<sup>&</sup>lt;sup>17</sup> 21 U.S.C. § 342(a)(4) (emphasis added).

<sup>&</sup>lt;sup>18</sup> United States v. Lazere, 56 F. Supp. 730, 733 (N.D. Iowa 1944); see also United States v. Swift & Co., 53 F. Supp. 1018, 1020 (M.D. Ga. 1943) (holding that "Congress intended that the word 'filthy', as used in the Act, should be construed to have its usual and ordinary meaning.").

<sup>&</sup>lt;sup>19</sup> Insanitary, MERRIAM-WEBSTER DICTIONARY, Online (2021).

<sup>&</sup>lt;sup>20</sup> Insanitary, LEXICO (OXFORD DICTIONARY), Online (2021).

<sup>&</sup>lt;sup>21</sup> FOOD AND DRUG ADMINISTRATION, Warning Letter, Lee-Way Farms, Inc. dba Blue Ridge Beef, MARCS-CMS 597944, June 26, 2020.

<sup>&</sup>lt;sup>22</sup> FOOD AND DRUG ADMINISTRATION, Warning Letter, Fresh Express, Inc. – Div. of Chiquita Brands, MARCS-CMS 609899, Oct. 20, 2020.

Moreover, in its Compliance Policy Guide for Dairies, the FDA states that "[m]any pathogens originate from the feces of the . . . animals themselves."<sup>23</sup> The Guide directly correlates such conditions to *Escherichia coli* (or "*E. Coli*")—known to cause diarrhea, cramping, nausea, and vomiting.<sup>24</sup> In addition, the Guide states that "the presence of *Escherichia coli* in (food products) . . . indicates insanitary conditions relating to contact with fecal matter."<sup>25</sup>

#### 2. The presence of standing water in food production facilities constitutes *"insanitary conditions."*

The FDA has warned of the risks posed by standing water in or near food production facilities. In a June 2020 letter to a pet food manufacturer, the FDA found "insanitary conditions" existed in circumstances very similar to those documented at Bravo:

The concrete floors of the kill floor (where whole animals are skinned and eviscerated), the cooler room (where carcasses are trimmed and held), and the grinder/mixing room (where pet food ingredients are ground, mixed, and packaged into finished product) are rough and pitted, with standing pools of water. These areas are not easily cleaned, creating a possible niche for undesirable microorganisms.<sup>26</sup>

In an October 2020 Warning Letter to a Michigan produce processing facility, the FDA remarked that:

[W]e observed standing water during the production of shredded cabbage. There was food debris on the floor in the standing water and workers walked through the water. Standing water fosters harborage of pathogens such as *Listeria monocytogenes*.<sup>27</sup>

In fact, health risks associated with standing water are so profound that the FDA has expressly identified the condition as a hallmark of "insanitary conditions" in other contexts. Although dealing specifically with Compounding Facilities, the FDA's industry guidance document includes "[s]tanding water or evidence of water leakage in the production area or adjacent areas" in its list of circumstances constituting "insanitary conditions."<sup>28</sup>

*3. Bravo's production of animal food in the presence of fecal matter and standing water renders its products "adulterated."* 

There is no question from the video evidence that Bravo prepared animal food in the presence of

<sup>&</sup>lt;sup>23</sup> FOOD AND DRUG ADMINISTRATION, Compliance Policy Guide, Sec. 527.300 Dairy Products – Microbial Contaminants and Alkaline Phosphate Activity (CPG 7106.08), p.3 (Dec. 2009).

<sup>&</sup>lt;sup>24</sup> E. coli, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/e-coli/symptoms-causes/syc-20372058 (last visited Jan. 4, 2021).

<sup>&</sup>lt;sup>25</sup> *Ibid*.

<sup>&</sup>lt;sup>26</sup> FOOD AND DRUG ADMINISTRATION, Warning Letter, Lee-Way Farms, Inc. dba Blue Ridge Beef, MARCS-CMS 597944, June 26, 2020.

 <sup>&</sup>lt;sup>27</sup> FOOD AND DRUG ADMINISTRATION, Warning Letter, Pearson Foods, Inc., MARCS-CMS 506517, Oct. 26, 2020.
<sup>28</sup> FOOD AND DRUG ADMINISTRATION, Insanitary Conditions at Compounding Facilities, Guidance for Industry, p.4

<sup>(</sup>Nov. 2020).

fecal matter and standing water. Mere feet from pools of standing water, feces, and blood, Bravo carelessly slaughtered a cow and prepared carcasses for use as animal food.

There is also no question that this violates federal law and merits enforcement action. But the FDA and Bravo have been here before. Despite FDA's repeated enforcement actions to address adulteration and insanitary conditions, Bravo has continued its unlawful conduct unabated. In light of this indifference to public health and to lesser enforcement measures, the FDA must vigorously enforce the FDCA and close Bravo's operations permanently.

## B. <u>The FDA Should Exercise its Broad Enforcement Powers to Punish Bravo to the Fullest</u> <u>Extent Allowable.</u>

# 1. The FDA should suspend Bravo's operations as expressly authorized by the FDCA.

Under the FDCA, the FDA is empowered to shutter operations at Bravo indefinitely. Under 21 U.S.C. § 350d(a)(1), "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States" shall be registered with the FDA. This registration is subject to indefinite suspension. According to the FDA's compliance and enforcement documents:

When a food product presents a reasonable probability of serious adverse health consequences or death to humans or animals, FDA can suspend a facility's registration to prevent it from introducing into interstate commerce food from the facility until FDA determines that adequate grounds do not exist to continue the suspension actions required by the order.<sup>29</sup>

Accordingly, the FDA is fully empowered to suspend Bravo's federal registration to produce food products. Given Bravo's egregious and repeated violations of federal law despite the FDA's more modest enforcement actions, the FDA should suspend the company's federal registration. Further, as Bravo has repeatedly failed to demonstrate "adequate grounds" to believe their practices are anything but unlawful and insanitary, the FDA should impose this suspension indefinitely.

2. The FDA should pursue criminal charges against Bravo as expressly authorized by the FDCA.

In addition to suspending Bravo's registration, the FDA is authorized to—and should—levy criminal charges as afforded by the FDCA, including the Act's steep and mandatory penalty provision. Under 21 U.S.C. § 333, "[a]ny person who violates a provision of (the section) shall be imprisoned for not more than one year or fined not more than \$1,000, or both."

For the past five years, Bravo has peddled contaminated products across the United States, endangering the health of countless humans and animals. The FDA has repeatedly called these issues to the attention of Bravo's operators, Amanda Lloyd and Joseph Merola, yet despite

<sup>&</sup>lt;sup>29</sup> *Compliance and Enforcement*, FOOD AND DRUG ADMINISTRATION, https://www.fda.gov/animal-veterinary/compliance-enforcement (last visited Nov. 30, 2020); *see also* 21 U.S.C. § 350d(b)(1).

numerous warnings, inspections, complaints, and recalls, they have continued to distribute hazardous products unabated. The continued operation of Bravo represents an unacceptable risk for the health and safety of consumers and their animals, including both pets and captive exotic animals. The FDA should suspend operations of the facility for good and levy criminal charges and fines against Amanda Lloyd, Joseph Merola, and the corporate entity itself.

### III. Bravo's Production of Animal Food in Insanitary Conditions Violates New Jersey Law and the NJDH Must Intervene to Permanently Close Bravo and End Its Continued Proliferation of Adulterated Products.

The NJDH must use its statutory enforcement power to permanently close Bravo and impose steep monetary penalties for its continued production of adulterated animal food. New Jersey law imposes strict sanitation requirements on food manufacturing facilities, including those producing animal food:

Every room in the building of a food, drug or cosmetic establishment shall be properly lighted, drained, plumbed and ventilated and the operations carried on therein shall be conducted in such a manner that the purity, quality and wholesomeness of the food, drug or cosmetic therein produced, manufactured, prepared, packed, stored, sold or distributed shall not be impaired.<sup>30</sup>

The law also provides that:

All food, drugs or cosmetics intended for distribution or sale in the process of production, manufacture, preparation, packing, storing or transportation shall be securely protected from flies, vermin, dust, dirt and so far as possible, by the use of all reasonable means, from all other foreign or injurious contamination.<sup>31</sup>

The NJDH can—and should—impose a host of consequences on Bravo for its continued violations.<sup>32</sup> First, the law requires monetary penalties between \$100 and \$1,000 for first violations and between \$200 and \$2,000 for the second and succeeding violations.<sup>33</sup> Moreover, each day of a continuing violation constitutes "an additional, separate and distinct offense."<sup>34</sup>

Second, the law imbues the NJDH with the authority to serve an order requiring Bravo to abate the ongoing violation.<sup>35</sup> Finally, the law grants the NJDH the ability to institute an action in the Salem County Superior Court to restrain Bravo's violations and to ask the court for any other relief the court shall deem proper.<sup>36</sup>

Bravo's production of animal food in insanitary conditions violates New Jersey's food safety laws and is punishable by fines and suspension of operations. Bravo has failed to conduct its

<sup>&</sup>lt;sup>30</sup> N.J.S.A. § 24:15-2.

<sup>&</sup>lt;sup>31</sup> N.J.S.A. § 24:15-5.

<sup>&</sup>lt;sup>32</sup> N.J.S.A. § 24:1-1.

<sup>&</sup>lt;sup>33</sup> N.J.S.A. § 24:5A-8(c).

<sup>&</sup>lt;sup>34</sup> Ibid.

<sup>&</sup>lt;sup>35</sup> N.J.S.A. § 24:15-11.

<sup>&</sup>lt;sup>36</sup> N.J.S.A. § 24:5A-9.

operations in a manner which prevents "foreign or injurious contamination,"<sup>37</sup> and by preparing carcasses for animal food in the presence of feces and standing water, Bravo has impaired the "purity, quality and wholesomeness of the food."<sup>38</sup>

The NJDH should impose monetary penalties to the maximum extent allowable, permanently suspend the company's operations, and petition the Salem County Superior Court to impose additional penalties including criminal charges and fines against Bravo's operators, Amanda Lloyd and Joseph Merola, and the corporate entity.

# IV. The Presence of *Listeria spp.* in Bravo's Horse Meat Indicates Conditions Suitable for the Survival and Growth of Dangerous Pathogens.

In addition to obtaining the aforementioned video evidence of animal food being prepared in insanitary conditions, Animal Outlook obtained a sample of horse meat from Bravo and commissioned laboratory testing that found it contained potentially harmful pathogens.

Both the FDCA and New Jersey's food safety laws prohibit the production and distribution of adulterated products. The FDCA prohibits "[t]he adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce."<sup>39</sup> A food—including animal food<sup>40</sup>—shall be deemed adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health."<sup>41</sup>

New Jersey law defines "food" broadly, explicitly including in the definition "articles used for food or drink for man *or other animals*."<sup>42</sup> New Jersey considers food "adulterated" if "it bears or contains any poisonous or deleterious substance which may render it injurious to health."<sup>43</sup>

On June 1, 2021, Joseph Merola provided the horse meat—packaged for consumer sale—after obtaining it from a freezer on Bravo's property. A picture of a portion of the horse meat obtained by Animal Outlook is below.

<sup>&</sup>lt;sup>37</sup> N.J.S.A. § 24:15-5.

<sup>&</sup>lt;sup>38</sup> N.J.S.A. § 24:15-2.

<sup>&</sup>lt;sup>39</sup> 21 U.S.C. § 331(b).

<sup>&</sup>lt;sup>40</sup> 21 U.S.C. § 321(f).

<sup>&</sup>lt;sup>41</sup> 21 U.S.C. § 342(a).

<sup>&</sup>lt;sup>42</sup> N.J.S.A. § 24:4-1(d) (emphasis added).

<sup>&</sup>lt;sup>43</sup> N.J.S.A. § 24:5-8(A)(1).



Animal Outlook commissioned laboratory testing on this horse meat. As depicted in the Certificate of Analysis below, the product was tested on June 7, 2021 and returned a presumptive positive result for *Listeria spp*.

	IEH Laboratories & Consulting Group			ATE OF ANALY <u>Animal Outlook</u> Contact: Will Lowrey P.O. Box 9773 Vashington, DC, D.C. 20016 Phone:(804) 307 9773		IEH Laboratories & Consulting Group IEH-Lake Forest Park 15300 Bothell Way NE Lake Forest Park, WA 98155 Phone:206-522-5432 Fax:206-524-4639 www.iehinc.com	
Trade secret / confidential commercial information       WO: 1174840     Rec. Date: 6/4/2021 16:43     Report Date: 6/7/2021     Report No: LFP-258335							
Lab Sample No	Customer Sample ID	Sample Desc	Customer Comments	LM (100g)	Listeria spp. (100g)	SAL (100g)	
1174840-001	1	Horse Meat	Bravo Packing horse meat	Negative	Presumptive Positive	Negative	
Test Method: LM = Listeria monocytogenes MB316.01 (AOAC-RI #021201), Listeria spp. = Listeria spp. MB316.01 (AOAC-RI #021201), SAL = Salmonella spp. MB217.01 (AOAC-RI # 100701) # 100701)							

*Listeria spp.* are foodborne pathogens that can be found in raw meat diets and "can result in significant health risks."<sup>44</sup> According to the FDA, "[a] positive test result for the presence of *Listeria spp.* . . . suggests that conditions are suitable for survival and/or growth of *L. monocytogenes*,"<sup>45</sup> a more serious infection that kills around 260 people each year.<sup>46</sup> While the

<sup>&</sup>lt;sup>44</sup> S. Kananub, et al, *Contamination factors associated with surviving bacteria in Thai commercial raw pet foods*, VET WORLD (Sep. 2020).

<sup>&</sup>lt;sup>45</sup> Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry, Draft Guidance, FOOD AND DRUG ADMINISTRATION, p.36 (2017), https://www.fda.gov/files/food/published/Draft-Guidance-for-Industry--Control-of-Listeria-monocytogenes-in-Ready-To-Eat-Foods-%28PDF%29.pdf (last visited June 23, 2021).

<sup>&</sup>lt;sup>46</sup> *Listeria* (*Listeriosis*), CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/listeria/index.html (last visited June 23, 2021); *see also* "Listeria," C.A. Batt, ENCYCLOPEDIA OF FOOD MICROBIOLOGY (Second Edition), 2014 (Stating that *Listeria spp.* "serves as an indicator whose presence is correlated to the presence of *L. monocytogenes.*").

presence of *Listeria spp.* alone does not render a product adulterated, it serves as an indicator of potentially dangerous conditions and warrants "corrective action . . . so that the product does not become adulterated."<sup>47</sup>

In short, the presence of *Listeria spp*. in a Bravo product obtained this month indicates that the filthy and insanitary conditions at Bravo are suitable for the survival and growth of far more harmful pathogens, including the deadly *Listeria monocytogenes*. The FDA's lengthy enforcement history plainly demonstrates that Bravo has repeatedly abdicated its food safety responsibilities, determined to continue slaughtering and processing animals in putrid, disgusting conditions at the expense of unwitting consumers and their animals. The FDA and NJDH must forcefully intervene and permanently end Bravo's unlawful operations.

# V. The FDA and NJDH Must Finally End Bravo's Repeated Violations of Federal and State Food Safety Laws

Time and again, the FDA and the NJDH have afforded Bravo opportunities to correct its unlawful business practices Yet repeatedly, Bravo has refused to do so, continuing to produce animal food in filthy, putrid conditions that jeopardize the health and welfare of any consumer or animal who comes into contact with Bravo's adulterated products. Bravo's conduct is prohibited by a myriad of federal and state food safety laws and the FDA and the NJDH are abundantly equipped to enforce these laws and close Bravo forever. Bravo's persistent repudiation of food safety laws and blatant disregard of lesser enforcement actions warrants the most severe penalties, including permanent closure, monetary penalties, and imprisonment. We urge the FDA and NJDH to act swiftly to protect consumers and their animals.

Animal Outlook is available and willing to assist with any enforcement actions. If you have any questions regarding this complaint, please contact me at (804) 307-4102 or wlowrey@animaloutlook.org. We look forward to your response.

Sincerely,

Mill haven

Will Lowrey Counsel Animal Outlook

cc:

Randy Pack, Director – Compliance Branch United States Food and Drug Administration Office of Regulatory Affairs, Human and Animal Food Division II East 6000 Metro Drive, Suite 101 Baltimore, Maryland 21215 randy.pack@fda.hhs.gov

<sup>&</sup>lt;sup>47</sup> *Listeria monocytogenes Regulations*, FOOD SAFETY AND INSPECTION SERVICE, https://www.fsis.usda.gov/sites/default/files/media\_file/2021-02/38\_IM\_Lm\_Regs.pdf (Mar. 2019).