UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, Plaintiff, v. ARROW RELIANCE INC. d/b/a DARWIN'S NATURAL PET PRODUCTS, a corporation, and GARY T. TASHJIAN, an individual, Defendants.	CASE NO. 2:26-cv-02805 COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), and this Court's inherent equitable authority, to permanently enjoin the defendants, Arrow Reliance Inc. d/b/a Darwin's Natural Pet Products ("Darwin's"), a corporation, and Gary T. Tashjian, an individual (collectively, "Defendants") from violating:

(a) 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering

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or causing to be delivered for introduction, into interstate commerce, articles of food, as defined by 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (a)(4);

(b) 21 U.S.C. § 331(uu), by operating a facility that is not in compliance with preventive controls requirements under 21 U.S.C. § 350g and its implementing regulation 21 C.F.R. § 507.34(a)(1);

(c) 21 U.S.C. § 331(k), by doing acts that result in articles of food becoming adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (a)(4) while such food is held for sale after shipment in interstate commerce;

(d) 21 U.S.C. § 331(dd), for failing to register as a food facility as required under 21 U.S.C. § 350d; and

(e) 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drugs, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(5).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS AND THEIR OPERATIONS

4. Darwin's is a pet food manufacturer incorporated in the State of Washington. Darwin's produces all of its raw dog food and raw cat food, among other products, at its headquarters and manufacturing facility located at 350 Treck Drive, Tukwila, WA 98188 ("Darwin's Facility" or "Facility"), within the jurisdiction of this Court.

5. Gary T. Tashjian is the President and founder of Darwin's. Defendant Tashjian is the

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person most responsible for Darwin's pet food operations. As President, Defendant Tashjian has ultimate responsibility for establishing a corporate-wide quality system for Darwin's manufacturing operations and overseeing adherence to its requirements. Furthermore, Defendant Tashjian has the duty, power, and authority to prevent, detect, and correct quality violations. Defendant Tashjian also approves capital expenditures; oversees marketing of Darwin's products and the company, including overseeing the company's website; and has authority to hire and fire employees. Defendant Tashjian performs these duties, as well as his other duties as President at the Darwin's Facility, within the jurisdiction of this Court.

DEFENDANTS' PRODUCTS

6. During their regular course of business, Defendants manufacture, process, prepare, pack, hold, and distribute articles of food within the meaning of 21 U.S.C. § 321(f), namely food for animals.

7. Defendants grind raw meat ingredients, including beef, lamb, turkey, chicken, duck, and pollock, and combine them with other ingredients before packaging, labeling, and freezing the food materials into finished raw pet food. Defendants produce approximately 85,000 lbs. of finished raw pet food per week. Consumers order Darwin's raw pet food via its website, www.darwinspet.com.

8. Defendants receive approximately 75% of their raw ingredients for their raw pet food in interstate commerce. For example, Defendants receive lamb from New Zealand and Australia; parsley flakes from Momence, Illinois; flaxseed oil from France; and turkey necks from Ponte Vedra Beach, Florida.

9. Darwin's distributes approximately 8% of its raw pet food directly from the Darwin's Facility to customers within Washington. Darwin's distributes approximately 36% of its raw pet

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food in interstate commerce directly from its Washington Facility to customers in other states. Darwin's ships the remaining approximately 56% of raw pet food in interstate commerce to third-party contracted warehouses located in Boyertown, PA and Denton, TX before distribution to customers in those regions (which extend beyond the borders of the states of Pennsylvania and Texas). Darwin's maintains ownership of the raw pet food that is held at the third-party warehouses.

HEALTH RISKS ASSOCIATED WITH RAW PET FOOD

10. FDA sampling and testing has repeatedly found the pathogen *Salmonella* in Defendants' finished, unopened raw pet food products. Of the 18 most recent samples of Darwin's raw pet food collected by FDA since 2023, 12 contained pathogens: nine contained *Salmonella*, one contained *Listeria monocytogenes* (*L. mono*), and two contained both *Salmonella* and *L. mono*.

11. A third party sampled and tested unopened packages of Darwin's raw pet food in 2025, finding that two lots contained *Salmonella* and one lot contained Shiga toxin-producing *E. Coli* (STEC).

12. *Salmonella*, STEC, and *L. mono* can cause illnesses—salmonellosis, STEC infection, or listeriosis, respectively—in both humans and pets. All three bacteria can be transmitted from pet food to people through handling, or from infected pets to their human companions.

13. Because Defendants' products are not intended to be cooked or subjected to another type of preparation that would destroy any pathogens before being served to pets, the bacterial pathogens in Darwin's raw pet food present a significant public health risk to both pets and people who handle the food and live with the pets.

14. Salmonellosis in humans is typically associated with diarrhea, fever, and abdominal cramps lasting four to seven days. Although the symptoms usually resolve without treatment in healthy adults, salmonellosis can cause severe dehydration and lead to death without prompt

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treatment in certain populations, including infants, young children, the elderly, pregnant women, and individuals with weakened immune systems. A small number of individuals with *Salmonella* infections develop reactive arthritis from an immune reaction to the infection, which can lead to chronic arthritis.

15. STEC infection in humans typically causes severe abdominal cramps, watery or bloody diarrhea, and vomiting. STEC infections can cause a complication called Hemolytic Uremic Syndrome (HUS), which can lead to kidney failure, permanent health problems, and death. HUS is most common among children younger than 10 years.

16. Listeriosis in humans is associated with fever, muscle aches, nausea, vomiting, and diarrhea. In vulnerable populations, infection with *L. mono* can cause blood poisoning, meningitis, and death. When *L. mono* infection spreads from a pregnant mother to her fetus, miscarriage or stillbirth results in one third of cases.

17. People can become infected with *Salmonella*, STEC, or *L. mono* if they touch contaminated pet food and do not thoroughly wash their hands afterward. *Salmonella*, STEC, and *L. mono* in pet food can cross-contaminate human food if the pet food is stored in the same refrigerator as human food or prepared on the same surfaces or with the same utensils as human food.

18. Dogs and cats infected with *Salmonella* from contaminated pet food can exhibit symptoms such as vomiting, diarrhea, fever, loss of appetite, and/or decreased activity level. In some cases, a *Salmonella* infection may spread from a dog's or cat's intestines to the blood stream, leading to death if not treated.

19. Dogs and cats infected with STEC can exhibit symptoms similar to humans such as watery or bloody diarrhea, and vomiting. The infection is rarely lethal in pets, but deaths have been reported in infected dogs.

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20. Dogs and cats infected with *L. mono* can exhibit symptoms such as diarrhea, vomiting, urinary tract infection, and tonsillitis. In serious cases, fever, miscarriage, and death are possible.

21. Dogs and cats infected with *Salmonella*, STEC, or *L. mono* can spread the pathogen to their human companions, even if the dogs and cats do not appear sick. Because an infected animal will shed *Salmonella*, STEC, or *L. mono* in its feces, these pathogens can be transmitted to people if they do not thoroughly wash their hands after cleaning up pet feces. Many pets groom themselves after they eat or defecate, and *Salmonella*, STEC, and *L. mono* can be transmitted from their mouths to surfaces that they subsequently lick, including a person's face or hands.

FDA'S INVESTIGATION

22. FDA inspected the Darwin's Facility in 2024, 2023, 2022, 2021, 2018-2019, and 2017-2018. FDA sampling and analysis of Darwin's finished raw pet food performed in conjunction with the 2024, 2023, 2022, 2018-2019, and 2017-2018 inspections revealed the presence of pathogenic bacteria, including *Salmonella* and *L. mono*, in Defendants' finished raw pet food products.

23. In September 2017, FDA analyzed an isolate from a sample of Darwin's unopened raw cat food following a report that a kitten died after eating Defendants' product. A necropsy confirmed that the kitten had a systemic bacterial infection with *Salmonella*. Whole genome sequencing[1] showed that *Salmonella* collected from the Darwin's cat food sample matched *Salmonella* in the kitten's liver.

[1] Whole genome sequencing is a scientific technique to identify the genomic (DNA) sequence of a bacterial isolate. A bacterial isolate is a single strain of bacteria separated from the mix of bacteria present in a sample. Once identified, isolates' genomic sequences can be compared to determine their relatedness.

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24. In November 2017, FDA collected samples of unopened Darwin's raw dog food products from five different lots in response to a consumer complaint that a dog became sick after eating Darwin's raw dog food products. Three samples tested positive for *Salmonella* and one of the samples also tested positive for *L. mono*.

25. In January 2018, FDA collected three samples of unopened Darwin's raw dog food, each from a different lot, following a consumer complaint of a dog diagnosed with salmonellosis after eating Darwin's raw dog food products. Two of the three samples tested positive for *Salmonella*, with one sample testing positive for two different serotypes of *Salmonella*.

26. In February 2018, an Iowa State diagnostic laboratory collected eight samples of unopened Darwin's raw dog food, each from a different lot, under a cooperative agreement with FDA. This testing found samples from four of the eight lots were positive for *Salmonella*. One sample also contained STEC, namely *E. Coli* O128.

27. FDA issued a warning letter to Darwin's on April 2, 2018, advising that lots of Darwin's raw pet food products were adulterated within the meaning of 21 U.S.C. § 342(a)(1). The April 2, 2018, letter noted contamination with *Salmonella* and STEC. Despite this warning, Defendants' raw pet food continues to test positive for pathogens.

28. In December 2018, FDA received a report of a diagnosed intestinal bacterial infection in a dog owner who fed their dog Darwin's raw dog food products. FDA obtained three samples of the unopened raw dog food from the owner's household, which had been manufactured in three separate lots. All three samples tested positive for *Salmonella*.

29. In July 2022, FDA received a consumer report that three cats in the same household became sick after eating Darwin's raw cat food. FDA tested three samples from unopened packages of Darwin's raw cat food, which were from three different lots and were collected from that

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household. Two of the three samples contained *Salmonella*.

30. In August 2022, after FDA analysis indicated that *Salmonella* was present in samples from unopened Darwin's raw cat food collected in response to the July 2022 consumer complaint of sickened cats, FDA recommended that Defendants recall the two affected lots. Darwin's declined to conduct the recall, and instead filed suit against FDA, seeking to enjoin the agency from notifying the public. *See Arrow Reliance, Inc. v. Woodcock*, No. 22-1057, 2022 WL 3104102 (W.D. Wash. Aug. 4, 2022). After the Court denied the temporary restraining order in August 2022, FDA issued a public health advisory regarding the affected lots of Darwin's pet food on its website. The Court denied Defendants' permanent injunction request on December 30, 2022.

31. FDA issued another warning letter to Darwin's on February 16, 2023, advising that lots of Darwin's raw pet food products were adulterated under 21 U.S.C. § 342(a)(1). The February 16, 2023, letter noted contamination with *Salmonella*. Despite this warning, Defendants' raw pet food continues to test positive for *Salmonella*.

32. In July 2023, FDA investigators collected four finished product samples of Darwin's raw pet food from four different lots at the firm's contracted distribution warehouse in Boyertown, PA. FDA analysis found that three out of the four samples contained *Salmonella*. FDA recommended that Defendants voluntarily recall the affected lots. Defendants declined to conduct a recall, and FDA subsequently issued another public health advisory on FDA's website.

33. In September 2023, a consumer reported to FDA that four cats in the same household became sick after eating Defendants' raw pet food products. FDA subsequently obtained a sample of unopened product from the consumer's home. FDA analysis identified *Salmonella* in the sample. On October 31, 2023, FDA made a formal request under 21 C.F.R. Part 7 that Defendants recall the *Salmonella*-containing lot. In its formal recall request letter, FDA advised Defendants: "If you do not

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voluntarily recall the above-mentioned product, FDA may take action against you, your firm, and any adulterated products distributed by your firm." Despite the formal recall request, Defendants did not conduct a recall.

34. In August 2024, FDA investigators collected environmental swab samples from the Darwin's Facility. FDA analysis found *Salmonella* in a swab sample from the inside of the hopper used to package Darwin's finished raw pet food.

35. In August 2024, FDA investigators collected six finished product samples of Darwin's raw pet food from six different lots at the firm's contracted distribution warehouse in Boyertown, PA. FDA analysis found that all six samples contained *Salmonella* and one sample contained both *Salmonella* and *L. mono*. FDA recommended that Defendants voluntarily recall the affected lots. When Defendants declined to conduct a recall, FDA issued a public health advisory. FDA issued Defendants a formal recall request letter on October 17, 2024. To date, Defendants have not conducted a recall.

36. In June 2025, FDA received a report of a four-year-old child who had fallen ill with STEC infection and associated HUS in August 2024. The child was hospitalized with severe illness and continues to face chronic kidney disease as a result of the STEC infection. The child's family fed its pet dog Darwin's raw pet food. FDA received third-party laboratory testing results of unopened Darwin's raw pet food from the family's home. The results indicate that the samples from two lots manufactured in May and June 2024 contained *Salmonella*. In addition, the results indicate that a sample from another lot that was manufactured in May 2024 contained STEC, namely *E. Coli* O157:H7. FDA recommended that Darwin's recall the affected lots. When Defendants declined to conduct a recall, FDA issued a public health advisory.

37. In August 2025, following a consumer report of a dog death, FDA collected

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unopened packages of Darwin's raw dog food from the consumer's home. FDA testing established that a sample from one lot contained *L. mono*, and a sample from another lot contained *L. mono* and *Salmonella*. Defendants agreed to notify relevant customers of the *L. mono* contamination in these lots. FDA issued a public health advisory because it was unable to verify the effectiveness of this notification, the notification did not include *Salmonella*, and Defendants did not agree to issue a press release.

38. Genomic sequences of clinical and food surveillance isolates are available in a public database maintained by the National Center for Biotechnology Information. FDA experts compared the genomic sequences of *Salmonella* isolates from the samples described above in paragraphs 23 through 37 against this database. Nine isolates from FDA samples collected in 2017, 2018, 2022, 2024, and 2025 from Darwin's raw pet food lots match isolates from human clinical samples within the database. The isolates in the human clinical samples are known to cause human illness. A match establishes that the strains in the FDA samples can also cause human illness.

39. FDA experts also compared the genomic sequence of the STEC isolated from a stool sample taken from the 4-year-old child described in paragraph 36 who fell ill with HUS against the genomic sequence of the STEC isolated from the Darwin's pet food purchased by the child's family prior to the child's illness. The genomic sequences were an exact match.

40. The consumer complaints listed above are only a fraction of all consumer complaints submitted to FDA related to Darwin's raw pet food products. In total, from 2016 through January 2026, FDA received 49 consumer complaints involving pets sickened after eating Darwin's raw pet food. Within these complaints, 34 dogs were reported sick, including five reported to have died, and 35 cats were reported sick, including four reported to have died. Most pet illnesses are never reported to FDA.

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ADULTERATION DUE TO CONTAINING A POISONOUS OR DELETERIOUS SUBSTANCE

41. Food is adulterated if it bears or contains a poisonous or deleterious substance, such as *Salmonella*, which may render the food injurious to health. 21 U.S.C. § 342(a)(1).

42. Defendants' raw pet food that contains *Salmonella* and/or STEC is adulterated under the meaning of 21 U.S.C. § 342(a)(1).

43. FDA previously issued warning letters to Darwin's on April 2, 2018, and February 16, 2023, advising that lots of Darwin's raw pet food products were adulterated under 21 U.S.C. § 342(a)(1). Despite these warnings, Defendants' raw pet food continues to test positive for pathogens.

44. Defendants have been and are violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery into interstate commerce, of articles of food within the meaning of 21 U.S.C. § 321(f) that are adulterated within the meaning of 21 U.S.C. § 342(a)(1).

ADULTERATION DUE TO PRODUCTION UNDER INSANITARY CONDITIONS

45. Food is adulterated 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. 21 U.S.C. § 342(a)(4).

46. Animal food manufacturers that are required to register with FDA as food facilities must adhere to FDA's current good manufacturing practice regulations for food for animals ("CGMP Regulations"), codified at 21 C.F.R. Part 507, Subpart B, which establish basic practices that must be followed and conditions that must be maintained during animal food manufacturing operations. *See* 21 C.F.R. §§ 507.14 through 507.28.

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47. The FDCA prohibits operating a facility that manufactures, processes, packs, or holds food for sale in the United States, if the owner, operator, or agent in charge is not in compliance with the hazard analysis and preventive controls requirements of 21 U.S.C. § 350g. *See* 21 U.S.C. § 331(uu).

48. The failure to comply with the CGMP Regulations is relevant to determining whether animal food is adulterated within the meaning of 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 507.1(a)(1)(ii).

49. Defendants manufacture, pack, and hold ready-to-eat raw pet food without eliminating *Salmonella*, STEC, and/or *L. mono* from the finished food as part of their manufacturing process.

50. During the 2024 inspection of the Darwin's Facility, FDA investigators swabbed the inside of Darwin's hopper used to package finished raw pet food. FDA analysis identified *Salmonella* on the swab.

51. During the 2024 inspection of the Darwin's Facility, FDA investigators noted dirty water and debris from dirty equipment pooling on top of containers of foam cleanser and sanitizer and falling into the opening of the containers. The cleanser and sanitizer were used in the sink to clean and sanitize equipment.

52. During the 2018 and 2024 inspections of the Darwin's Facility, FDA investigators observed that parts of equipment that come into direct contact with food were pitted and rusted and observed deep cut marks on cutting board surfaces. Investigators noted in 2024 that these cut marks remained discolored after cleaning and sanitation.

53. During the 2018 and 2024 inspections of the Darwin's Facility, FDA investigators observed Darwin's employees who were handling raw pet food touch unsanitized materials and

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surfaces and continue handling raw pet food without sanitizing their hands.

54. During the 2024 inspection of the Darwin's Facility, FDA investigators observed drops of condensation falling from the ceiling of the production room onto sanitized equipment.

55. During the 2024 inspection of the Darwin's Facility, FDA investigators observed aerosolized water from employees hosing off the grinder, meat prep table, and uncleaned floors blowing onto exposed ready-to-eat raw pet food.

56. During the 2024 inspection of the Darwin's Facility, FDA investigators observed that the floor throughout the production room and the base of a pillar were damaged and pitted, with water, blood, and raw ingredients accumulating in the damaged areas of the floor.

57. Defendants' raw pet food is adulterated within the meaning of 21 U.S.C. § 342(a)(4), because 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.

58. Defendants have been and are failing to comply with the CGMP Regulations in that they:

a. do not ensure that adequate precautions are taken so that Darwin's Facility operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal-food packaging materials, as required by 21 C.F.R. § 507.25(a)(5);

b. do not construct and maintain the Darwin's Facility in such a manner that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination, as required by 21 C.F.R. § 507.17(b)(2);

c. fail to maintain the animal food contact surfaces of the Darwin's Facility's equipment and utensils used for manufacturing, processing, packing, and holding animal food to protect animal food from being contaminated, as required by 21 C.F.R.

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§ 507.22(a)(4)(iii); and

d. fail to keep the Darwin's Facility clean and in good repair to prevent animal food from becoming adulterated, as required by 21 C.F.R. § 507.19(a).

59. Defendants have been and are violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery into interstate commerce, of articles of food within the meaning of 21 U.S.C. § 321(f) that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

FAILURE TO FOLLOW PREVENTIVE CONTROLS REGULATION

60. For purposes of 21 U.S.C. § 350g, the term "facility" means a facility that is required to register under 21 U.S.C. § 350d. 21 U.S.C. § 350g(o)(2).

61. Defendant Tashjian is an owner, operator, and/or agent in charge of the Darwin's Facility. Defendant Tashjian is required to register the Darwin's Facility under 21 U.S.C. § 350d because Darwin's manufactures, processes, packs, or holds food at the facility for consumption in the United States, and no exemption under 21 C.F.R. § 1.226 applies. *See* 21 U.S.C. § 350d; 21 C.F.R. § 1.225.

62. As authorized by 21 U.S.C. § 350g(n), FDA promulgated the hazard analysis and preventive controls regulation for animal food, and these requirements are codified at 21 C.F.R. Part 507, subparts A, C, D, E, and F ("Preventive Controls Regulation"). Under the Preventive Controls Regulation, owners, operators, or agents in charge of a facility are required to identify and evaluate the hazards for the type of food manufactured, processed, packed, or held by such facility and adequately identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented, and the animal food manufactured, processed, packed, or held by the facility will not be adulterated under 21 U.S.C.

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§ 342. 21 U.S.C. § 350g; 21 C.F.R. §§ 507.33(a)(1) and 507.34(a)(1).

63. The Preventive Controls Regulation defines "significantly minimize" to mean "reduce to an acceptable level, including to eliminate." 21 C.F.R. § 507.3.

64. FDA has advised industry that *Salmonella*, pathogenic *E. Coli* (such as STEC), and *L. mono* are foodborne pathogens associated with pet food. *See* FDA, Guidance for Industry #245, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, https://www.fda.gov/media/110477/download.

65. During FDA's 2023 and 2024 inspections of the Darwin's Facility, FDA investigators observed that Defendants prepared hazard analyses identifying contamination with pathogens such as *Salmonella*, *E. Coli*, and *L. mono* as a possible hazard but failed to adequately identify preventive controls to significantly minimize or prevent this hazard in Darwin's ready-to-eat raw pet food.

66. For example, since at least 2022, Defendants have been using peracetic acid and a cold storage program, among other supposed pathogen control measures. Nevertheless, FDA's analyses found *Salmonella* and *L. mono* in samples from twelve finished lots of Defendants' raw pet food that had been produced with these measures in place (samples collected after August 23, 2022), and a third party's analysis found *Salmonella* and STEC in samples from three other finished lots produced in 2024, indicating that these pathogens are not being significantly minimized or prevented. *See* paragraphs 33–37 above. As demonstrated by the repeated presence of these pathogens, Defendants' measures were insufficient to minimize or prevent the presence of pathogens in Darwin's products. FDA made Defendants aware of the repeated presence of pathogens in Darwin's raw pet food, yet Defendants have not remedied their conduct.

67. Defendant Tashjian has failed and continues to fail to identify and implement preventive controls to significantly minimize or prevent the hazard of contamination with pathogens

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such as *Salmonella*, STEC, and *L. mono* in their finished product, as required by 21 C.F.R. § 507.34(a)(1).

68. Defendants have been and are violating 21 U.S.C. § 331(uu) by operating a facility that manufactures, processes, packs, or holds food for sale in the United States, without complying with the hazard analysis and preventive controls requirements of 21 U.S.C. § 350g.

69. Defendant Tashjian's failure to follow the Preventive Controls Regulation is also relevant to determining whether Defendants' animal food is adulterated within the meaning of 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 507.1(a)(1)(ii).

FAILURE TO REGISTER AS A FOOD FACILITY

70. The owner, operator, or agent in charge of a facility as defined at 21 C.F.R. § 1.227 engaged in manufacturing, processing, packing, or holding of food for consumption in the U.S. must register with FDA unless the facility qualifies for one of the exemptions in 21 C.F.R. § 1.226. *See* 21 C.F.R. § 1.225(a); 21 U.S.C. § 350d.

71. The Darwin's Facility meets the 21 C.F.R. § 1.227 definition of a facility because it is an "establishment, structure, or structures under one ownership at one general physical location . . . that manufactures/processes, packs, or holds food for consumption in the United States." 21 C.F.R. § 1.227.

72. FDA's February 16, 2023, Warning Letter notified Defendant Tashjian that the Darwin's Facility is subject to the registration requirement at 21 U.S.C. § 350d. Despite this warning, Defendant Tashjian has not registered the Darwin's Facility.

73. Defendant Tashjian has been and is violating 21 U.S.C. § 331(dd) because he has failed to register the Darwin's Facility under 21 C.F.R. § 1.225, and none of the exemptions at 21 C.F.R. § 1.226 applies.

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INTRODUCTION OF UNAPPROVED NEW ANIMAL DRUG INTO INTERSTATE COMMERCE

74. The FDCA defines an article as a "drug" if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1).

75. The intended use of a product can be shown by labeling claims, advertising, or oral or written statements by persons legally responsible for the labeling of an article or by their representatives. 21 C.F.R. § 201.128.

76. Darwin's website is controlled by Defendants. Statements on the Darwin's website indicate that Darwin's raw pet food is intended to prevent, cure, and/or treat disease in animals, including, but not limited to the following:

- "After about a month [of switching to Darwin's dog food], you will see improvements in your dog's overall health, as their immune system becomes stronger and better able to fight off disease. . . If your dog has a chronic illness like diabetes, skin allergies, or arthritis, you may notice some symptoms start to disappear without medications." (https://www.darwinspet.com/why-raw/see-the-difference.html, accessed August 5, 2026).
- "Many customers tell us they see dramatic changes in their pets after switching to Darwin's" including "a sharp decrease in common diseases and conditions like arthritis and diabetes." (https://www.darwinspet.com/why-raw/benefits-of-raw.html, accessed August 5, 2026).
- "There is no question that changing our dog Cory over to a raw, all-natural diet was the reason that his seizures stopped." (https://www.darwinspet.com/blogs/health-issues/canine-epilepsy, accessed August 5, 2026).

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- "Prevent Feline Urinary Tract Infections (UTI) and Irritable Bowel Disease (IBD) by Feeding Raw." https://www.darwinspet.com/blog/switch-raw-diet-your-cat.html, accessed August 5, 2026).

77. Defendants' raw pet food products are drugs because the statements on Darwin's website demonstrate that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals. 21 U.S.C. § 321(g)(1).

78. A drug is a "new animal drug" if it is intended for use in animals and it is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. 21 U.S.C. § 321(v)(1).

79. Defendants' raw pet food products are new animal drugs because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. 21 U.S.C. §§ 321(g)(1), 321(v)(1).

80. Unless a new animal drug is approved or authorized by FDA as described in 21 U.S.C. § 360b(a)(1)(A)-(D) or exempt because it is investigational as described in 21 U.S.C. § 360b(a)(3), the new animal drug is an unsafe new animal drug and is adulterated. *See* 21 U.S.C. §§ 360b(a), 351(a)(5).

81. Because Defendants' new animal drugs are not approved or authorized by FDA as described in 21 U.S.C. § 360b(a)(1)(A)-(D) or exempt as investigational as described in 21 U.S.C. § 360b(a)(3), they are unsafe and adulterated. 21 U.S.C. §§ 360b(a), 351(a)(5).

82. Defendants have been and are violating 21 U.S.C. § 331(a) by introducing or

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delivering for introduction into interstate commerce, and/or causing the introduction or delivery into interstate commerce, of adulterated new animal drugs.

ONGOING CONDUCT

83. Based on the facts and violations of law alleged in this Complaint, the United States has reason to believe that, unless restrained by the Court, Defendants will continue to violate:

a. 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of pet food that are adulterated within the meaning of 21 U.S.C. § 342(a)(1);

b. 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of pet food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

c. 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States, without complying with the hazard analysis and preventive controls requirements of 21 U.S.C. § 350g;

d. 21 U.S.C. § 331(k), because they cause animal food held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342(a)(4);

e. 21 U.S.C. § 331(dd), because they have failed to register the Darwin's Facility under 21 C.F.R. § 1.225, and none of the exemptions at 21 C.F.R. § 1.226 applies; and

f. 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce articles of new animal drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(5).

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Count I
Against All Defendants
(21 U.S.C. § 331(a))

84. All previous paragraphs are incorporated as if set forth here.

85. Defendants have violated, and unless enjoined will continue to violate, 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of pet food that are adulterated within the meaning of 21 U.S.C. § 342(a)(1).

Count II
Against All Defendants
(21 U.S.C. § 331(a))

86. All previous paragraphs are incorporated as if set forth here.

87. Defendants have violated, and unless enjoined will continue to violate, 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of pet food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

Count III
Against All Defendants
(21 U.S.C. § 331(uu))

88. All previous paragraphs are incorporated as if set forth here.

89. Defendants have violated, and unless enjoined will continue to violate, 21 U.S.C. § 331(uu) by operating a facility that manufactures, processes, packs, or holds food for sale in the United States, without complying with the hazard analysis and preventive controls requirements of 21 U.S.C. § 350g.

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Count IV
Against All Defendants
(21 U.S.C. § 331(k))

90. All previous paragraphs are incorporated as if set forth here.

91. Defendants have violated, and unless enjoined will continue to violate, 21 U.S.C. § 331(k) because they cause animal food held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and/or 21 U.S.C. § 342(a)(4).

Count V
Against Defendant Tashjian
(21 U.S.C. § 331(dd))

92. All previous paragraphs are incorporated as if set forth here.

93. Defendant Tashjian has violated, and unless enjoined will continue to violate, 21 U.S.C. § 331(dd), because he has failed to register the Darwin's Facility under 21 C.F.R. § 1.225, and none of the exemptions at 21 C.F.R. § 1.226 applies.

Count VI
Against All Defendants
(21 U.S.C. § 331(a))

94. All previous paragraphs are incorporated as if set forth here.

95. Defendants have violated, and unless enjoined will continue to violate, 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of new animal drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(5).

PRAYER FOR RELIEF

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WHEREFORE, the United States of America respectfully requests that this Court:

I. Order that 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, cease manufacturing, processing, preparing, packing, holding, or distributing articles of animal food, unless and until Defendants' facilities, methods, processes, and controls used to manufacture, process, prepare, pack, hold, and distribute articles of animal food are established, operated, and administered in conformity with the FDCA and applicable regulations, in a manner acceptable to FDA.

II. Permanently restrain and enjoin under 21 U.S.C. § 332(a) Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any article of animal food that is adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (a)(4);

B. Violating 21 U.S.C. § 331(uu), by operating a food facility without complying with preventive controls as required by 21 U.S.C. § 350g and the Preventive Controls Regulation;

C. Violating 21 U.S.C. § 331(k), by causing articles of animal food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (a)(4);

D. Violating 21 U.S.C. § 331(dd), by operating a food facility without registering as required under 21 U.S.C. § 350d; and

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E. Violating 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any article of new animal drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(5).

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the manufacture, processing, preparing, packing, holding, and distribution of Defendants' products to ensure continuing compliance with the terms of the injunction, and that the Defendants bear the costs of such inspections at the rates prevailing at the time the inspection(s) are accomplished.

IV. Award Plaintiff costs incurred in pursuing this action, including the costs of investigation to date. And,

V. Order such other and further equitable relief as this Court deems just and proper.

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DATED this 7th day of August, 2026.

Respectfully submitted,

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