UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS,
2901 Shepherd Street
Mount Rainier, MD 20712 (Montgomery County),

FOOD ANIMAL CONCERNS TRUST,
3525 W. Peterson Avenue
Chicago, IL 60659,

NATURAL RESOURCES DEFENSE COUNCIL, INC.,
40 West 20th Street
New York, NY 10011,

PUBLIC CITIZEN,
1600 20th Street NW
Washington, DC 20009,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, MD 20993 (Montgomery County),

ROBERT M. CALIFF, in his official capacity as Commissioner, U.S. Food and Drug Administration,
10903 New Hampshire Avenue
Silver Spring, MD 20993 (Montgomery County),

CENTER FOR VETERINARY MEDICINE,
7500 Standish Place
Rockville, MD 20855 (Montgomery County),

TRACEY H. FORFA, in her official capacity as Acting Director, Center for Veterinary Medicine,
7500 Standish Place
Rockville, MD 20855 (Montgomery County),

Defendants.

No. 8:23-cv-176

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Antibiotic resistance—the ability of disease-causing bacteria to defeat the drugs designed to kill them—is one of the greatest threats to public health. Each year, more than 2.8 million antibiotic-resistant infections occur in the United States. These difficult-to-treat infections contribute to as many as 162,000 deaths annually. The antibiotic resistance crisis is fueled in significant part by the misuse and overuse of antibiotics in industrial livestock and poultry production.

2. A group of health advocates petitioned the U.S. Food and Drug Administration (FDA) in 2016 to ban disease-prevention uses of medically important antibiotics in livestock and poultry because such uses pose a grave threat to people's health. FDA arbitrarily denied the Petition five years later without responding to the Petition's central argument and evidence of human health harm. The Court should vacate FDA's unlawful action and remand the Petition to the agency with instruction to grant the Petition or, in the alternative, to provide a new, reasoned decision that addresses the public health concerns at the crux of the Petition.

3. Approximately two-thirds of medically important antibiotics sold in the United States—antibiotics including penicillins and tetracyclines that are vital for treating diseases in humans—are sold for use in food-producing animals. These antibiotics are often administered to entire herds or flocks in feed or water, to prevent infections that tend to occur when animals are kept in cramped, unsanitary conditions common in factory farms.

4. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., charges the FDA with regulating the use of antibiotics in livestock. *Id.* § 360b. The Act requires FDA to withdraw approval for an animal drug if FDA finds, among other things, that the drug is not shown to be safe for the uses for which it was approved. *Id.* § 360b(e)(1). According to an FDA guidance document referred to as "Guidance for Industry No. 152," an animal drug is "safe" if "there is reasonable certainty of no harm to human health from the proposed use of the drug in food-producing animals."

5. In 2016, some of the Plaintiffs in this suit petitioned FDA under 21 C.F.R. § 10.25(a), requesting that the agency ban the use of medically important antibiotics for disease prevention in healthy livestock and poultry. The Petition appended a robust body of scientific, medical, and public health evidence, including FDA's own findings, that overwhelmingly conclude that these drug uses are contributing to the development of antibiotic-resistant bacteria that can be (and are) transferred to humans.

6. Several years passed with no response from FDA. In 2020, the petitioners supplemented the Petition with additional research that routine administration of medically important antibiotics to entire herds for disease prevention is not safe for human health, and that such use remains high in beef, pork, and turkey production.

7. FDA denied the Petition in February 2021. The agency acknowledged the "risk that antimicrobial resistance poses to public health." But the agency disclaimed any numerical targets for reducing antibiotic use and explained that it was focused instead "on supporting judicious use" of antibiotics. "Judicious use," as set out in FDA's

guidance documents, is based on considerations of animal health: it encourages veterinarians to evaluate factors including evidence of the drug's efficacy in animals.

8. Judicious use under FDA's voluntary guidance documents does not include analysis of *human* health effects of feeding antibiotics to entire herds or flocks over long periods of time. The agency's decision did not respond to the Petition's core argument that eliminating the preventive use of medically important antibiotics in food-producing animals is necessary to safeguard public health.

9. FDA's final response to the Petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the Administrative Procedure Act (APA), 5 U.S.C. § 706(2).

10. Plaintiffs Alliance of Nurses for Healthy Environments, Food Animal Concerns Trust, Natural Resources Defense Council, and Public Citizen seek a judgment declaring that FDA's denial of the Petition violates the APA, and an order to grant the Petition, or in the alternative, to vacate and remand FDA's decision and for the agency to review anew the Petition.

JURISDICTION AND VENUE

11. This case arises under the APA, 5 U.S.C. §§ 701-706. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1) because Defendant FDA resides in this judicial district.

13. Assignment to the Southern Division of this Court is appropriate because Plaintiffs include a non-governmental entity residing in this division, and Defendants are a federal agency and federal officials. L.R. 501.4(a)(ii).

14. This Court may award Plaintiffs all necessary injunctive relief pursuant to the APA, 5 U.S.C. § 706(2)(A), and may award declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

PARTIES

Plaintiffs

15. Plaintiff Alliance of Nurses for Healthy Environments ("Alliance of Nurses") is a nonprofit national nursing organization located in Mount Rainier, Maryland, that focuses on the intersection of health and the environment. Alliance of Nurses educates and leads the nursing profession by advancing research, incorporating evidence-based practice, and influencing policy. Among the Alliance of Nurses' policy focuses is the impact of food systems on public health. For the past ten years, Alliance of Nurses has worked with health and advocacy organizations to support reducing non-therapeutic antibiotic use in livestock production because Alliance members have seen increasing numbers of patients with antibiotic-resistant infections. Alliance members have also provided education and testimony to state and federal legislators on policies to address antibiotic resistance.

16. Alliance of Nurses' members, including Dr. Kathy Murphy, Mr. David Buchheit, and Dr. Barbara Ann M. Messina, have health interests in reducing the use of antibiotics for disease prevention in livestock.

17. Plaintiff Food Animal Concerns Trust (FACT) is a national nonprofit organization based in Chicago, Illinois. Since its founding in 1982, FACT has been dedicated to improving the welfare of farm animals, addressing public health problems that come from the production of meat, milk, and eggs, and broadening opportunities for family farmers. FACT conducts research and makes science-based recommendations to agricultural, public health, and environmental organizations and to federal regulatory agencies. The organization advocates for responsible use of animal drugs and publishes reports and "score cards" to educate the public and urge regulators to phase out the routine, nontherapeutic use of medically important antibiotics in food-producing animals.

18. Plaintiff Natural Resources Defense Council (NRDC) is a nonprofit environmental and public health advocacy organization headquartered in New York, New York, with hundreds of thousands of members nationwide. NRDC engages in research, advocacy, and litigation to improve the regulation of harmful substances in food and consumer products, including halting the misuse and overuse of antibiotics and other antibacterial products. NRDC also works to promote sustainable agricultural practices.

19. NRDC's members, including Mr. Dennis Haller, have health, recreational, aesthetic, and other interests in reducing the use of antibiotics for disease prevention in livestock.

20. Plaintiff Public Citizen is a nonprofit public interest organization headquartered in Washington, DC, with members in all fifty states and the District of

Columbia. Since its founding in 1971, Public Citizen has worked before Congress, regulatory agencies, and in the courts to advance the interests of its members on a wide range of consumer protection issues. Among other things, Public Citizen promotes research-based, system-wide changes in health care policy and provides oversight concerning drugs, medical devices, doctors, hospitals, and occupational health.

21. Public Citizen's members, including Ms. Stephanie Donne and Mr. Scott Nelson, have health interests in reducing the use of antibiotics for disease prevention in livestock.

Defendants

22. Defendants FDA and Robert M. Califf, in his official capacity as Commissioner of FDA, are charged by the Federal Food, Drug, and Cosmetic Act with protecting the public health by ensuring that veterinary drugs are safe. The Act requires FDA to withdraw approval of new animal drugs that are not shown to be safe.

23. Defendants FDA's Center for Veterinary Medicine (CVM) and Tracey H. Forfa, in her official capacity as Acting Director of CVM, are charged by the Federal Food, Drug, and Cosmetic Act and its implementing regulations with withdrawing approval of new animal drugs that are not shown to be safe.

24. This Complaint refers to Defendants FDA, Robert M. Califf, CVM, and Tracey H. Forfa individually and collectively as "FDA."

STATUTORY AND REGULATORY BACKGROUND

25. The Secretary of the U.S. Department of Health and Human Services, through the Commissioner of FDA, 21 U.S.C. § 393(d)(2), regulates antibiotics in animal feed as

"new animal drugs" under section 512 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b.

26. FDA is required to withdraw its existing approval of an animal drug if new information shows the drug is not safe. Under the Federal Food, Drug, and Cosmetic Act, the agency "shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application" if the agency finds that "experience or scientific data" or "new evidence not contained" in the original application "evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved." 21 U.S.C. § 360b(e)(1).

27. The Commissioner of FDA has delegated some of the statutory responsibilities under 21 U.S.C. § 360b to the Director of CVM. This delegation includes the authority to issue notices of hearings on proposed withdrawals of animal drug approvals and to revoke and amend regulations for animal drugs and medicated feed mill licenses. FDA, Staff Manual Guides, Vol. II—Delegations of Authority § 1410.503 (2014); *see* 21 C.F.R. § 5.84 (1998) (withdrawn and re-promulgated in the Staff Manual Guides); *see also* 21 U.S.C. § 360b(m) (requiring licenses for certain facilities producing drug-containing animal feed); 21 C.F.R. pt. 515 (same).

28. FDA's regulations allow any interested person to petition FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a).

FACTUAL BACKGROUND

I. The misuse and overuse of antibiotics in livestock contribute to the proliferation of antibiotic-resistant superbugs, threatening human health

29. Livestock producers have been adding low doses of antibiotics to the feed of healthy animals since the 1950s. Today, approximately two-thirds of all medically important antibiotics sold in the United States are for use in food-producing animals. A significant percentage of these antibiotics are administered flock- or herdwide at subtherapeutic levels—that is, below the dose used to treat disease—and over extended periods of time, to prevent diseases that occur more frequently when animals are kept in cramped, dirty conditions common to intensive animal facilities.

30. The use of antibiotics in this manner is far more likely to create antibiotic-resistant bacteria than short-term use of antibiotics in individual animals or targeted groups of animals, and thus poses a higher risk to public health. This litigation and the underlying Petition to FDA do not concern targeted, short-term uses of antibiotics to treat animals that are sick.

31. Scientists have long understood that bacteria are capable of developing resistance to antibiotics. Natural selection plays a significant role: when an antibiotic drug is introduced to a population of bacteria, the bacteria that are susceptible to the drug die off, but bacteria already resistant to the drug survive and reproduce, increasing the proportion of resistant bacteria in the population.

32. Bacteria exposed to antibiotics also develop mutations that make them resistant. When bacteria develop resistance, they can cause hard-to-treat diseases.

33. Bacteria may become resistant to multiple classes of antibiotics. The use of any one drug may select for groups of genes that provide resistance not only to the original drug but to other chemically related drugs as well. The bacteria that carry resistance genes can transfer those genes to other bacteria, allowing bacteria that have never been exposed to antibiotics to become resistant to them. Bacteria can also transfer resistance genes to bacteria in different species and genera, and from bacteria that do not cause human illness to bacteria that do.

34. Public health officials agree that the overuse of medically important antibiotics in livestock fuels the rapid proliferation of antibiotic-resistant bacteria that threaten human health. These bacteria include common sources of foodborne illness in people, such as Salmonella, Campylobacter, and E. coli. Antibiotic-resistant bacteria in food are particularly dangerous for children: most foodborne infections affect children younger than five.

35. Resistant bacteria from industrial animal facilities can spread to humans who are exposed to meat products or livestock. Data indicate that retail meat products are frequently contaminated by Salmonella, Campylobacter, E. coli, and other bacteria that are resistant to multiple classes of antibiotics. Various epidemiological studies have confirmed that these bacteria have been transferred to people.

36. People are also exposed to antibiotic-resistant bacteria from animals in other ways. Studies show that farmworkers can be exposed to resistant bacteria through contact with animals and may inadvertently bring these bacteria home to their families and communities. Antibiotic-resistant bacteria may also spread from industrial

livestock facilities through air, dust, animal waste, or insects and rodents that pass through these facilities.

37. Widely respected public health entities, including the World Health Organization and the Infectious Diseases Society of America, have called for action to reduce antibiotic use by halting the preventive use of drugs in entire herds or flocks.

38. FDA has known for at least five decades that subtherapeutic use of antibiotics in animal feed poses risks for public health. FDA first approved the use of antibiotics as animal feed additives in the 1950s to increase the speed of animal growth and prevent disease. In the following years, FDA became concerned that long-term use of antibiotics in animals may drive the development of antibiotic-resistant bacteria.

39. In the early 1970s, an FDA task force recommended that antibiotics used in human medicine be prohibited from use in animal feed unless they met safety criteria established by FDA, and that several specific drugs, including tetracyclines and penicillins, be reserved for treating sick animals unless certain safety findings were made for subtherapeutic use. 37 Fed. Reg. 2444, 2445 (Feb. 1, 1972). Based on the task force's findings, FDA proposed in 1973 to withdraw all approvals for subtherapeutic uses of antibiotics in animal feed unless drug sponsors submitted data within the next two years to resolve the human safety issues. *See* 38 Fed. Reg. 9811, 9813 (Apr. 20, 1973).

40. In 1977, after reviewing the submitted information, FDA proposed to withdraw most subtherapeutic uses of penicillins and tetracyclines in animal feed, because those uses were not shown to be safe for human health. *See* 42 Fed. Reg. 43,770, 43,770 (Aug. 30, 1977); 42 Fed. Reg. 56,264, 56,264 (Oct. 21, 1977). Despite decades of

further study that failed to establish safety, FDA took no further action to withdraw the drug use approvals.

II. FDA's voluntary guidance, the 2016 Citizen Petition, and FDA's denial

41. In 2012, partly in response to petitions asking FDA to withdraw approval of medically important antibiotics, FDA issued Guidance for Industry No. 209. This guidance document discouraged the use of antibiotics "to promote growth or improve feed efficiency." The guidance suggested that livestock and pharmaceutical companies administer medically important antibiotics (1) only when necessary to ensure the animals' health and (2) only with veterinary oversight. Guidance No. 209, at 21-22. Like other FDA guidance documents, it did not establish legally enforceable obligations.

42. In 2013, the agency issued Guidance for Industry No. 213, asking pharmaceutical companies to voluntarily remove growth-promotion uses from labels of medically important antibiotics and change the use conditions of over-the-counter products to require veterinary oversight, either through a prescription or a veterinary feed directive (a prescription filled by an animal feed mill). Guidance No. 213, at 6-7. Guidance No. 213 also recommended the "voluntary adoption of judicious use principles," *id.* at 5, in which veterinarians authorize the use of antibiotics in feed after evaluating factors such as animal stress from overcrowding and transport, whether there is evidence of drug efficacy, and if a reasonable alternative to administering antibiotics exists, *id.* at 7. In the following years, the industry ceased growth-promotion uses. Disease-prevention uses, however, continue.

43. In 2016, consumer, environmental, and health advocacy groups, including Plaintiffs FACT, NRDC, and Public Citizen, as well as Earthjustice, filed a petition with FDA asking the agency to withdraw approval of the uses of certain medically important antibiotics for disease-prevention or growth-promotion purposes in livestock and poultry. The classes of antibiotics identified were macrolides, lincosamides, penicillins, streptogramins, tetracyclines, aminoglycosides, and sulfonamides.

44. The Petition explained why FDA's voluntary program to reduce antibiotic use would not adequately reduce use and protect human health. Disease prevention represents a significant, avoidable share of antibiotic use in livestock production. These uses pose the same health risks as antibiotics used for the now-discontinued growth promotion purposes—both involve low doses administered to entire herds or flocks for extended periods of time.

45. The Petition also explained that allowing disease prevention use creates a loophole for continued use of medically important antibiotics at low levels to promote animal growth. And the Petition noted that veterinary oversight would similarly fail to address the crisis: veterinary associations have been openly skeptical that antibiotic use in food animals presents a human health hazard and cannot be expected to take steps voluntarily to reduce antibiotic use. The Petition asked FDA to expedite withdrawing approval for these antibiotic uses, whether through a formal or informal hearing process.

46. Several years passed without a response from FDA. During this time, pursuant to Guidance No. 213, drug companies revised product labels to eliminate

growth-promotion use and require veterinarian oversight for disease-prevention use. The elimination of growth-promotion uses and transition to veterinary oversight appear to have led to a drop in sales of medically important antibiotics in 2016 and 2017. However, the downward trend did not continue—instead, since 2017, sales have gone back up. In 2020, according to FDA's data, six million kilograms (13.23 million pounds) of medically important antibiotics were sold, reflecting an eight-percent increase from 2017 sales. In short, FDA action to date has failed to sufficiently reduce the misuse and overuse of these antibiotics for disease prevention.

47. In 2020, the advocacy groups supplemented the 2016 Petition with new studies and reports. The supplemental Petition acknowledged that growth-promotion uses had been phased out and thus focused only on disease-prevention uses. It pointed out that, by authorizing continued use of medically important antibiotics for disease prevention in entire herds or flocks, FDA allows more animals—and therefore, more bacteria—to be exposed to antibiotics, elevating the risk that resistance will develop and spread.

48. FDA denied the Petition in February 2021.

49. The agency "generally agree[d]" with the Petition's description of how the use of antibiotics "can contribute to the development and proliferation of antimicrobial resistant bacteria." FDA Denial at 4. FDA disclaimed, however, any goal of reducing antibiotic use, stating that it "has not focused on setting overall targets for reductions in antimicrobial sales or use." *Id.* at 8. The agency took this stance despite acknowledging in earlier guidance documents that it was recommending voluntary measures intended

to "reduce overall . . . drug use levels, thereby reducing" the "selection pressure" that spurs the development of antibiotic-resistant bacteria. Guidance No. 209, at 22.

50. Instead of setting numerical goals to reduce levels of antibiotic use, FDA highlighted the "successful implementation" of voluntary measures to shift antibiotics from over-the-counter use to use under veterinary oversight. FDA Denial at 3. FDA touted the decrease of antibiotic sales in 2016 and 2017 following the phase-out of growth-promotion uses. *Id.* at 7. The agency downplayed the fact that antibiotic use went back up in the following years, and that sales for animal use continue to dominate total sales of medically important antibiotics in the United States.

51. In response to the Petition's request that FDA withdraw disease-prevention uses of antibiotics important for human medicine, FDA explained that it "supports the judicious use of antimicrobials" under veterinary oversight "for the treatment, control, or prevention" of disease. *Id.* at 3. A use is "judicious," according to FDA, if it is not "unnecessary or inappropriate." Guidance No. 209, at 3. The agency asked veterinarians to consider issues like "inadequate ventilation" and "stress of animal transport" in determining whether animals are at risk of developing a disease and thus should be preventively fed antibiotics. Guidance No. 213, at 7. These and other factors enumerated in FDA's guidance documents—the drug's efficacy, whether use is consistent with "accepted veterinary practice" and "linked to a specific [disease-causing] agent," and if "reasonable alternative[]" treatments exist, *see* FDA Denial at 11—all relate to "the health of food-producing animals," *id.* None of the factors address whether continued

use of medically important antibiotics in this manner—low doses administered to entire herds or flocks over lengthy periods—is safe for human health.

52. The Federal Food, Drug, and Cosmetic Act requires FDA to withdraw approval for an animal drug if FDA finds that the drug is not shown to be safe for human health. *See* 21 U.S.C. § 360b(e)(1); Guidance No. 152. FDA's framework for "judicious use" is not equivalent to a finding that such use is safe for human health, and FDA has not found that "judicious use" will reduce the volume of antibiotics used in animals and decrease the development of antibiotic-resistant bacteria. Although FDA elsewhere recognizes the human health interests at stake, *see* Guidance No. 209, at 20, the agency's decision fails to address the Petition's core assertion: to safeguard human health, FDA must significantly reduce the vast quantity of medically important antibiotics used in livestock by halting the subtherapeutic, herd- and flock-wide use of these antibiotics for disease prevention.

III. FDA's denial of the Petition harms Plaintiffs and their members

53. FDA's denial of the Petition harms the members of Plaintiffs Alliance of Nurses, NRDC, and Public Citizen. The members' health is continually threatened by their exposure to meat and poultry products contaminated with bacteria resistant to antibiotics. As a result, some of Plaintiffs' members have reduced their meat consumption or spend more time or money than they otherwise would to buy meat from animals raised without antibiotics.

54. The recreational and aesthetic interests of Plaintiffs' members are also harmed by FDA's refusal to withdraw approval for disease-prevention uses of antibiotics in

livestock. For example, members who live in areas with industrial livestock facilities avoid swimming, fishing, and other activities because they are concerned about exposure to drug-resistant bacteria from animal waste that contaminates the water and air.

55. Plaintiffs' members include medical professionals, and the overuse of antibiotics in livestock jeopardizes the health of these members and their patients. The increasing prevalence of antibiotic-resistant infections forces doctors to prescribe higher doses of antibiotics, or second- or third-generation antibiotics that have a higher risk of side effects. Patients with antibiotic-resistant infections may become sicker than they otherwise would have been, have a greater risk of poor health outcomes, and face higher healthcare costs due to more expensive antibiotics, longer hospital stays, and more interventions to treat the infection. Doctors and nurses are also at higher risk of contracting resistant infections themselves from contact with patients in clinics and hospitals.

56. Although Plaintiffs' members can and do take measures to reduce their exposure to antibiotic-resistant bacteria, it is impossible to avoid exposure entirely. Once antibiotic resistance develops in one community, it can easily spread to other locations and establish itself in healthcare facilities. The threats to Plaintiffs' members can be redressed only by reducing the systemic overuse of medically important antibiotics for disease prevention in food animals.

57. The risk that Plaintiffs' members will be exposed to antibiotic-resistant bacteria through eating contaminated meat, or via environmental pathways or

healthcare settings, and the costs that some members incur to limit the feared exposure, are traceable to FDA's denial of the Petition.

58. If FDA were to grant the Petition and withdraw approval for subtherapeutic uses of medically important antibiotics in animal feed, the prevalence of bacteria in livestock with resistance to those drugs would stop increasing and would likely decrease. As a result, Plaintiffs' members would face a reduced risk of contracting a drug-resistant infection from eating contaminated meat, working with livestock, recreating in rivers and streams near livestock facilities, and through other environmental pathways.

59. FDA's decision also impairs Plaintiff FACT's mission of advocating for food safety, helping farmers adopt humane practices, and ensuring consumers can make healthy food choices. Because of FDA's Petition denial, FACT expends much of its resources raising awareness of the problem of antibiotics use and resistance, monitoring government agency activity around antibiotic use in food-producing animals, and pressuring companies to adopt practices that are more protective than FDA regulations require. This prevents FACT from allocating organizational resources to other programs and goals, including reforming farm practices to prevent foodborne pathogens, researching links between regenerative agriculture and food safety, and ensuring more equitable access to healthy food.

60. The frustration of Plaintiff FACT's mission and drain on its resources are traceable to FDA's decision and would be redressed if FDA were to grant the Petition.

CLAIM FOR RELIEF

61. The APA empowers this Court to "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

62. FDA's denial of the 2016 Citizen Petition is a final agency action.

63. FDA failed to provide a reasoned explanation for denying the Petition, failed to consider an important aspect of the problem, and offered an explanation for its decision that runs counter to the evidence before the agency.

64. FDA's denial of the Petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in contravention of the APA, 5 U.S.C. § 706(2).

REQUEST FOR RELIEF

Plaintiffs respectfully request that this Court:

a. Declare that FDA's denial of the Petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

b. Set aside FDA's denial of the Petition;

c. Remand the Petition to FDA with an instruction to grant the Petition or, in the alternative, for prompt reconsideration of the Petition;

d. Award Plaintiffs their reasonable costs and attorneys' fees; and

e. Grant such other and further relief as the Court deems just and proper.

Dated: January 24, 2023

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