IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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| NATURAL RESOURCES DEFENSE COUNCIL, INC.,<br><br>Plaintiff,<br>v.<br><br>U.S. FOOD AND DRUG ADMINISTRATION,<br><br>Defendant. | ) | Case No. 20-cv-7703 |

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

1. Plaintiff Natural Resources Defense Council, Inc. (NRDC), brings this case to compel Defendant United States Food and Drug Administration (FDA) to disclose records it has failed to disclose in violation of the Freedom of Information Act (FOIA), 5 U.S.C. § 552.

2. On May 30, 2020, NRDC submitted a FOIA request to FDA, requesting the disclosure of records relating to FDA's failure to withdraw approval of the use of medically important antibiotics in livestock and poultry for disease prevention.

3. FDA has failed to respond to NRDC's FOIA request within the statutory time period.

4. NRDC seeks a declaration that FDA has violated FOIA by failing to promptly produce all responsive, nonexempt documents. NRDC respectfully requests that the Court order FDA to disclose, without further delay, all responsive records. NRDC also requests that the Court retain jurisdiction to ensure that all nonexempt records are produced.

## JURISDICTION AND VENUE

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (federal question) and 5 U.S.C. § 552(a)(4)(B) (FOIA).

6. Venue is proper in the U.S. District Court for the Southern District of New York because NRDC resides and has its principal place of business in this district. 5 U.S.C. § 552(a)(4)(B); 28 U.S.C. § 1391(e)(1), (c)(2).

## THE PARTIES

7. Plaintiff NRDC is a national nonprofit environmental and public health membership organization with hundreds of thousands of members. NRDC engages in research, advocacy, public education, and litigation related to protecting public health and the environment. NRDC has a long history of disseminating information of public interest, including information obtained through FOIA.

8. Defendant FDA is a federal agency within the meaning of FOIA, 5 U.S.C. §§ 551(1), 552(f)(1), and possesses or controls the records that NRDC seeks.

## STATUTORY FRAMEWORK

9. FOIA requires federal agencies to release information to the public upon request, unless any one of nine statutory exemptions applies. 5 U.S.C. § 552(a)-(b).

10. Within twenty business days of an agency's receipt of a FOIA request, the agency must "determine . . . whether to comply" with the request. *Id.* § 552(a)(6)(A)(i); *see also* 21 C.F.R. § 20.41(b). The agency must "immediately notify" the requester "of such determination and the reasons therefor." 5 U.S.C. § 552(a)(6)(A)(i)(I); *see also* 21 C.F.R. § 20.41(b).

11. In specified "unusual circumstances," an agency may extend the twenty-day time limit for responding to a FOIA request by up to ten working days. 5 U.S.C. § 552(a)(6)(B)(i); *see also* 21 C.F.R. § 20.41(b)(3)(i)(A). In such cases, the agency must provide "written notice" to the requester setting forth the unusual circumstances and the date by which it expects to make the determination. 5 U.S.C. § 552(a)(6)(B)(i); *see also* 21 C.F.R. § 20.41(b)(3)(i)(A). The agency may further extend its time

to respond only upon a showing of "exceptional circumstances" or written notice and negotiation of an alternative time frame with the requestor. 5 U.S.C. § 552(a)(6)(C)(i); *see also* 21 C.F.R. § 20.41(b)(3)(i)(B).

12. Once an agency determines that it will comply with the request, it must "promptly" release responsive, nonexempt records to the requester. 5 U.S.C. § 552(a)(6)(C)(i). These records must be disclosed upon request "regardless whether any justification or need for such records" is shown. 21 C.F.R. § 20.20(c).

13. The agency must provide requested records at no or reduced cost "if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii); *see also* 21 C.F.R. § 20.46(a)(1)-(2).

14. If the agency violates FOIA's time limits, the requester is deemed to have exhausted their administrative remedies and may sue immediately. 5 U.S.C. § 552(a)(6)(C)(i). District courts may enjoin an agency from withholding agency records and "order the production of any agency records improperly withheld." *Id.* § 552(a)(4)(B).

## FACTUAL BACKGROUND

15. Public health authorities, including FDA, have known for decades that the misuse and overuse of medically important antibiotics in livestock and poultry production contributes to the development and proliferation of antibiotic-resistant bacteria. In the last decade, scientific studies have confirmed that bacteria exposed to antibiotics develop mutations or acquire genes that make them resistant to antibiotics. Studies have also confirmed that bacteria that carry resistance genes can transfer those genes to other, nonresistant bacteria; that people who live near or come into contact with farm facilities are more likely to carry antibiotic-resistant bacteria and develop antibiotic-resistant infections; and that the use of antibiotics in livestock increases the prevalence of resistant bacteria in the environment and the general human population.

16. FDA is charged with regulating the use of antibiotics in livestock. FDA has approved the use of antibiotics in animal feed for nontherapeutic purposes—such as routine disease prevention—since the 1950s. These antibiotics—macrolides, licosamides, penicillins, streptogramins, tetracyclines, aminoglycosides, and sulfonamides—are generally given to animals at "subtherapeutic" levels (i.e., doses too low to

treat disease). Some of these antibiotics, including penicillin and tetracyclines, are also important in human medicine.

17. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b(e)(1)(A)-(B), FDA is required to withdraw approval for an animal drug if FDA finds that the drug is not shown to be safe for the uses for which it was approved.

18. On September 13, 2016, NRDC petitioned FDA pursuant to 21 C.F.R. § 10.30, requesting that it withdraw its approval of uses of medically important antibiotics in livestock and poultry for disease prevention. Despite the statutory requirement that FDA withdraw approvals for animal drugs it knows not to be safe, and the mounting scientific research confirming the risks posed by the routine use of medically important antibiotics in livestock and poultry production, FDA has yet to respond to NRDC's petition.

19. NRDC, its members, and the public at large have a strong interest in understanding whether FDA has any plans to address the growing threat of antibiotic resistance, particularly in light of the mounting research confirming the role played by the routine use of antibiotics in livestock and poultry for disease prevention.

20. On May 30, 2020, to better inform the public and its members, NRDC submitted a FOIA request to FDA seeking records related to FDA's failure to respond to NRDC's petition, via FDA's FOIA On-Line Request Portal, in accordance with the agency's FOIA regulations and guidance.

21. NRDC's request sought the following records:

1. All records since September 13, 2016, reflecting FDA's work to respond to the NRDC citizen petition lodged under docket number FDA-2016-P-2737;

2. A chronological listing of all petitions submitted to FDA's Center for Veterinary Medicine (CVM) pursuant to 21 C.F.R. § 10.30 that: (a) are currently pending disposition; or (b) have been approved or denied since November 5, 2014. This list should include: "(1) [t]he docket number; (2) [t]he date the petition was filed by the Division of Dockets Management; (3) [t]he name of the petitioner; (4) [t]he subject matter involved; . . . (5) [t]he disposition of the petition," *see* 21 C.F.R. § 10.30(l)(1)-(5); and (6) "the priority assigned to the petition," *id.* § 10.30(e)(1)(ii);

3. All records citing to or discussing the World Health Organization's 2017 recommendation to restrict use of medically important antimicrobials in food-producing animals for disease prevention;

4. All records referencing, discussing, or quantifying domestic sales and distribution of macrolides, licosamides, penicillins, streptogramins, tetracyclines, aminoglycosides, and sulfonamides for use in food-producing animals in 2019. These records include Form FDA 3744 "Antimicrobial Animal Drug Distribution" reports submitted by sponsors—developers, producers, and sellers—of animal drug products. They also include drafts of FDA's annual *Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*; and

5. All records of any reassignment or shifting of CVM personnel to matters pertaining to FDA's response to the COVID-19 pandemic.

22. NRDC also requested that FDA waive any fees for the search and production of the requested records, pursuant to FOIA's and FDA's fee waiver provisions, since disclosure of the requested records is in the public interest because "it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii); *see also* 21 C.F.R. § 20.46(a)(1)-(2). On June 2, 2020, FDA emailed NRDC to acknowledge receipt of the FOIA request.

23. On June 17, 2020, FDA sent NRDC an email which purported to disclose records responsive to the first paragraph in NRDC's FOIA request—namely, "[a]ll records since September 13, 2016, reflecting FDA's work to respond to the citizen petition lodged under docket number FDA-2016-P-2737." FDA's response consisted of six hyperlinks to dockets on Regulations.gov: one of these was a hyperlink to NRDC's own September 13, 2016 rulemaking petition, and the other five were entirely unrelated to the subject matter of the request—for example, Docket No. FDA-2020-D-1442, "Concerns Related to the Use of Clove Oil as an Anesthetic for Fish."

24. On June 17, 2020, NRDC emailed FDA to remind the agency that it had yet to provide a final response as to the remaining four

categories of requested documents (items 2-5 in NRDC's request), and that FDA's response to item 1 was inadequate and incomplete.

25. On June 22, 2020, FDA responded to NRDC's June 17, 2020 email, stating that CVM "is searching for items 2-5 and will respond once your request comes up in the queue." FDA further responded that it had sent "everything" responsive to item 1.

26. FDA's response to NRDC's May 30, 2020 request (Request No. FDA-2020-4153) was due within twenty business days of May 30, 2020—i.e., by June 26, 2020. *See* 5 U.S.C. § 552(a)(6)(A)(i), (6)(C)(i).

27. NRDC has received no further records or emails from FDA.

28. FDA has failed to respond to NRDC's FOIA request within the time mandated by FOIA. FDA has also failed to make a determination on NRDC's fee waiver request.

**CLAIM FOR RELIEF**

29. Plaintiff NRDC incorporates by reference all preceding paragraphs.

30. NRDC has exhausted its administrative remedies.

31. NRDC has a statutory right under FOIA to receive a determination on its requests by the statutory deadlines, which have

passed, and to promptly obtain all records that are responsive to its requests and that are not exempt from disclosure.

32. FDA has violated its duty under FOIA, 5 U.S.C. § 552(a), to respond to NRDC's request for records and a fee waiver, and to release all nonexempt, responsive records by the statutory deadline.

33. Because FDA violated FOIA's statutory deadlines and requirement to disclose all nonexempt, responsive records, NRDC has a right to obtain responsive records from FDA without being assessed any search or duplication fees. *Id.* § 552(a)(4)(A)(viii)(I). NRDC is also entitled to a fee waiver because the disclosure is likely to contribute significantly to public understanding of government activities and is not in NRDC's commercial interest. *Id.* § 552(a)(4)(A)(iii).

**REQUEST FOR RELIEF**

NRDC respectfully requests that this Court enter judgment against FDA as follows:

1. Declare that FDA violated FOIA by failing to produce all nonexempt records responsive to NRDC's FOIA requests by the statutory deadline;

2. Order FDA to disclose all responsive, nonexempt records to NRDC without further delay, and without charging search or duplication costs;

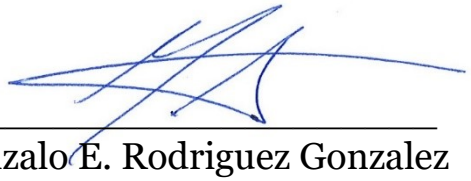
3. If FDA contends that any responsive records are exempt or partially exempt from disclosure under FOIA, order FDA to produce a *Vaughn* index identifying any withheld records or parts thereof and the basis for the withholdings, and require FDA to prove that its decision to withhold or redact any such records is justified by law;

4. Award NRDC its costs and reasonable attorneys' fees;

5. Grant such other relief that the Court considers just and proper; and

6. Retain jurisdiction over this case.

Respectfully submitted,



Gonzalo E. Rodriguez Gonzalez
CA Bar No. 322913
Natural Resources Defense Council
111 Sutter Street, Floor 21
San Francisco, CA 94104
Telephone: (415) 875-6110
Email: grodriguez@nrdc.org
*Pro Hac Vice admission pending*

Michelle A. Newman
NY Bar No. 5414685

40 West 20th Street, Floor 11
New York, NY 10011
Telephone: (212) 727-2700
Email: mnewman@nrdc.org

Selena Kyle
IL Bar No. 6311573
202 North Wacker Dr., Suite 1600
Chicago, IL 60606
Telephone: (312) 651-7906
Email: skyle@nrdc.org