IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR FOOD SAFETY, 303 Sacramento Street, 2nd Floor San Francisco, CA 94111 *Plaintiff,* vs. UNITED STATES FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue Silver Spring, MD 20993 *Defendant.*	Case No. 13-cv-1541 COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT

Plaintiff Center for Food Safety alleges as follows:

I. NATURE OF ACTION

1. Plaintiff Center for Food Safety (CFS) brings this action under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Through a FOIA request, CFS has sought records from Defendant United States Food and Drug Administration (FDA) related to the beta-agonist drug zilpaterol. Defendant has violated FOIA by failing to adequately respond to the request within the statutorily prescribed time limit, failing to disclose the requested documents, and unlawfully withholding the requested information. CFS now asks the Court to order Defendant to respond to the request and produce all responsive agency records improperly withheld from the Plaintiff.

II. JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to FOIA, 5 U.S.C. § 552(a)(4)(B). This Court also has jurisdiction over this action under 28 U.S.C. § 1331 (federal question).

3. This Court has the authority to grant declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*

4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e) because no real property is involved in this action and Plaintiff is incorporated and has its principal place of business in this district. Venue is also proper under 5 U.S.C. § 552(a)(4)(B).

5. This Court has the authority to award costs and attorneys' fees under 28 U.S.C. § 2414 and 5 U.S.C. § 552(a)(4)(E).

III. PARTIES

6. Plaintiff CFS is a national nonprofit organization incorporated in Washington, D.C., with offices in Washington, D.C.; Portland, Oregon; and San Francisco, California. CFS represents more than 350,000 farmer and consumer members throughout the country who support safe, sustainable agriculture.

7. CFS is not a commercial enterprise for purposes of the fee waiver provisions of FOIA. *See* 5 U.S.C. § 522(a)(4)(A)(iii). CFS is dedicated to protecting human health and the environment by curbing the proliferation of harmful food production technologies, such as factory farms or Concentrated Animal Feeding Operations (CAFOs), and instead promoting sustainable agriculture. CFS's mission is to protect the public's right to know how their food is produced. CFS utilizes regulatory actions, citizen engagement, legislation, and when necessary, litigation, to promote transparency and accountability in the factory farm industry.

8. A cornerstone of CFS's mission is to inform, educate, and counsel its members and the public on the harm done to human health, animal welfare, and the environment by industrial agriculture, including the use of beta-agonist drugs such as zilpaterol in food animal production. To support its mission, CFS regularly seeks, uses, and distributes public records.

9. Defendant FDA is an agency of the United States, within the meaning of 5 U.S.C. § 552(f)(1), and has a duty to provide public access to documents in its possession consistent with the requirements of FOIA. It has possession of, and control over, the records that CFS seeks, and is denying Plaintiff access to its records in contravention of federal law.

IV. STATUTORY FRAMEWORK

10. FOIA promotes open government by providing every person with a right to request and receive federal agency records. 5 U.S.C. § 552(a)(3)(A), (f).

11. In furtherance of its design to encourage open government, FOIA imposes strict deadlines on agencies to provide responsive documents to FOIA requests. 5 U.S.C. § 552(a)(6)(A).

12. An agency must comply with a FOIA request by issuing a determination within twenty days after receipt of the request. 5 U.S.C. § 552(a)(6)(A)(i).

13. The determination "must at least inform the requester of the scope of the documents that the agency will produce, as well as the scope of the documents that the agency plans to withhold under any FOIA exemptions." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 186 (D.C. Cir. 2013).

14. An agency must immediately notify the requester of the determination and the reasons for it, and of the right of such person to appeal an adverse determination. The agency has twenty days to make a determination with respect to any appeal. 5 U.S.C.

§ 552(a)(6)(A)(ii).

15. An agency's failure to comply with any timing requirements is deemed constructive denial and satisfies the requester's requirement to exhaust administrative remedies. 5 U.S.C. § 552(a)(6)(C)(i).

16. A FOIA requester who exhausts administrative remedies may petition the court for injunctive and declaratory relief from the agency's continued withholding of public records. 5 U.S.C. § 552(a)(4)(B).

V. FACTUAL BACKGROUND

17. Zilpaterol is a beta-agonist drug that helps cattle grow to greater "finishing weights" in the weeks before slaughter. It is widely used in U.S. meat production. Zilpaterol is linked to health problems in animals, including reluctance to move, walking gingerly, and signs of lameness. It has also been linked to difficulty walking or inability to move in cattle delivered to slaughter plants.

18. On January 4, 2013, CFS submitted a FOIA request to FDA related to zilpaterol. Specifically, CFS requested:

> Any and all documents concerning zilpaterol or zilpaterol hydrochloride, which is also known as and sold as Zilmax, (collectively hereinafter "zilpaterol"), including but not limited to the following:
>
> 1. Any and all documents concerning the testing or study of zilpaterol prior to, and since, FDA's approval of zilpaterol as a new animal drug.
>
> 2. Any and all documents concerning reports of any adverse reactions or adverse events for zilpaterol, including but not limited to the reports, studies and other information pertaining to safety and effectiveness of new animal drugs required to be submitted to FDA by 21 C.F.R. § 514.80.
>
> 3. Any and all documents concerning zilpaterol's effects or potential effects on animal welfare, animal health, human health, or the environment. (This request specifically includes a request for any and all documents

pertaining to FDA's analysis of zilpaterol under the National Environmental Policy Act (NEPA) or finding of no significant impact thereunder).

4. Any and all documents pertaining to communications with Environmental Protection Agency (EPA) concerning zilpaterol, including any documents concerning potential animal or human health issues associated with use of zilpaterol in food-producing animal feed.

5. Any and all documents concerning the approval of zilpaterol as a new animal drug, whether through a new animal drug application (NADA) or an abbreviated new animal drug application (ANADA).

6. Any and all documents concerning recalls of zilpaterol.

7. Any and all FDA warning letters concerning zilpaterol.

8. Any and all documents concerning tolerance levels for zilpaterol.

9. Any and all documents concerning withdrawal periods for zilpaterol.

10. Any and all documents concerning acceptable daily intake for zilpaterol.

11. Any and all documents concerning the labeling of zilpaterol.

12. Any and all documents concerning communications or meetings with industry (including but not limited to the pharmaceutical, agriculture or food industries) or trade groups (including but not limited to pharmaceutical, agriculture or food trade groups) about zilpaterol.

13. Any and all documents concerning new animal drug applications or abbreviated new animal drug applications for zilpaterol (including but not limited to NADA 141-276, NADA 141-278, NAD[A] 141-280, NAD[A] 141-282, ANADA 200-479, ANADA 200-480, ANADA 200-483).

14. Any and all documents concerning changes of sponsorship for zilpaterol.

15. Any and all documents concerning communications or meetings with the Codex Committee on Residues of Veterinary Drugs in Foods (the "Committee") or any member of the Committee, including but not limited to the Committee's 2008 expert report.

16. Any and all documents concerning complaints or comments from members of the public concerning zilpaterol.

17. Any and all documents concerning FDA's ability to collect fees for

> certain animal drug applications, and for the establishments, products and sponsors associated with these and previously approved animal drug applications, in support of the review of animal drugs under the Animal Drug User Fee Act of 2003 (21 U.S.C. s. 379j-11 and j-12) for zilpaterol.

21. On January 29, 2013, FDA's Office of Executive Secretariat (OES) notified CFS by letter that it did not have any responsive records. It also stated that CFS "may hear from other FDA offices regarding the remainder of [its] request." It did not indicate the scope of the documents that the agency expected to produce or withhold.

22. On January 30, 2013, OES confirmed that CFS's "request is also pending in the Center for Veterinary Medicine and therefore the Office of the Executive Secretariat will not be the only office responding to [CFS]."

23. On February 5, 2013, the Division of Dockets Management (DDM) within FDA provided CFS with responsive records. It did not indicate the scope of the documents that the agency expected to produce or withhold. Nor did it indicate whether any more records would be forthcoming from other divisions, or whether it constituted FDA's final response.

24. On March 29, 2013, CFS contacted John Matthew Hyder at the Center for Veterinary Medicine (CVM) by email to inquire as to the status of the FOIA request. Mr. Hyder informed CFS that he was no longer in CVM, and instructed CFS to contact Laura Bradbard or Nadine Steinberg regarding the request.

25. On April 1, 2013, CFS contacted Ms. Bradbard and Ms. Steinberg by email to inquire as to the status of the FOIA request. Neither person replied to CFS's inquiry.

26. On April 3, 2013, Laura Alvey of CVM notified CFS by email that "[t]he Center for Veterinary Medicine is in receipt of your FOIA request, 2013-147. It is approximately #100 in our queue of pending FOI requests." Immediately thereafter CFS attempted to schedule a

phone call with Ms. Alvey to discuss the request. After some correspondence on April 3 regarding the date and time of the phone call, Ms. Alvey stopped responding. The phone call never took place.

27. Since February 5, 2013, CFS has not received any additional records in response to this request. Since April 3, 2013, CFS has not been contacted by any individual from any division within FDA.

28. To date, CFS has not received any response from CVM.

29. Plaintiff CFS has fully exhausted its administrative remedies. Administrative remedies are deemed exhausted whenever an agency fails to comply with the applicable time limits, as stated by 5 U.S.C. § 552(a)(6)(C). Plaintiff now turns to this Court to enforce the remedies and public access to agency records guaranteed by FOIA.

CAUSE OF ACTION

Violation of the Freedom of Information Act

30. Plaintiff re-alleges and incorporates by reference the allegations set forth in paragraphs 1-29 in the complaint as if fully set forth herein.

31. CFS made a proper FOIA request for information relating to the animal drug zilpaterol. 5 U.S.C. § 552(a)(3)(A).

32. FDA's failure to respond adequately to the request within statutory timelines is a violation of FOIA, 5 U.S.C. § 552, and the agency's own regulations promulgated thereunder.

33. FDA's failure to disclose the requested documents is a violation of FOIA, 5 U.S.C. § 552, and the agency's own regulations promulgated thereunder.

34. FDA's wrongful withholding of the requested documents is a violation of FOIA, 5 U.S.C. § 552, and the agency's own regulations promulgated thereunder.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Order FDA to expeditiously produce all records requested by Plaintiff;

B. Declare as unlawful FDA's failure to respond to Plaintiff's FOIA request;

C. Declare as unlawful FDA's failure to disclose records that Plaintiff has requested;

D. Exercise close supervision over FDA as it processes Plaintiff's request;

E. Award to Plaintiff all costs and reasonable attorneys' fees as provided in 5 U.S.C. § 552(a)(4)(E) or any other law; and

F. Grant other and further relief as the Court may deem just and proper.

Dated this 7th day of October, 2013.

Respectfully submitted,

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