UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN HEALTH RESEARCH GROUP, 1600 20th Street NW Washington, DC 20009, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993-0002, Defendant.	)	Case No. 20-cv-204

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This action is brought under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, to compel the U.S. Food and Drug Administration (FDA) to produce records responsive to a FOIA request concerning the FDA's approval of the prescription drug Balversa.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B). Venue is proper under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

PARTIES

3. Plaintiff Public Citizen Health Research Group (HRG) is a division of Public Citizen Foundation, a non-profit public interest organization that, among other things, works to promote government transparency and accountability and to advance consumer protection. HRG submitted the FOIA request at issue in this case.

4. Defendant FDA is an agency within the Department of Health and Human Services. The FDA has possession of and control over the records that HRG seeks.

FACTS

Background

5. As part of the FDA's review of applications for approval of new drugs, the FDA conducts scientific reviews within different disciplines (for example, pharmacology, medicine, and statistics) for each application.

6. When, following the completion of this review process, the FDA approves a new drug application, it publicly posts online a so-called "action package." The action package is a compilation of the key decision documents from the FDA's review of the application. The action package includes review documents prepared by the reviewers in each discipline and various other documents generated during the review of the application.

7. Historically, each discipline provided a separate application review document, which the FDA included in the action package posted online.

8. In June 2019, the FDA announced that had begun to utilize a "new integrated review process and documentation template," whereby one "collaborative document" would contain "clinical, clinical pharmacology, biostatics, toxicology" and other discipline review information. New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication, 84 Fed. Reg. 30,733, 30,735 (June 27, 2019).

9. In the action package for the prescription drug Balversa, the FDA publicly posted online a multidiscipline review that contained information concerning reviews from different disciplines.

10. The Balversa multidiscipline review provided a list of FDA personnel who participated in conducting the various reviews. Among those listed were Clinical Reviewers Dow-Chung Chi (Efficacy), Michael Brave (Safety), and Elaine Chang (Real World Evidence); Clinical Team Leader and Cross-Disciplinary Review Leader Chana Weinstock; Statistical Reviewer Wei Zhang; Statistical Team Leader Lijun Zhang; and Office of Clinical Pharmacology Team Leaders Pengfei Song, Jingyu (Jerry) Yu, and Yuching Yang.

FOIA Request

11. On October 2, 2019, HRG submitted a FOIA request to the FDA for "[a]ny documents written by" the persons listed in paragraph 10, above, for Balversa "from which analyses, recommendations, or any other information was extracted, excerpted, and/or summarized for inclusion in [the] multidiscipline review" of Balversa. HRG also requested a waiver of processing fees.

12. On October 8, 2019, the FDA acknowledged HRG's FOIA request and assigned it control number 2019-9516.

13. On December 18, 2019, HRG requested that the FDA provide it with an estimated timeframe for the processing of this FOIA request.

14. That same day, the FDA responded that this FOIA request was in the complex queue and that the average wait time for FOIA requests in the complex queue is 18–24 months.

15. More than 20 working days have passed since HRG submitted this FOIA request, and the FDA has neither made a final determination nor produced any records in response to this FOIA request.

CLAIM FOR RELIEF

16. HRG has a statutory right under FOIA, 5 U.S.C. § 552(a)(3)(A), to the records it requested, and the FDA has no legal basis for failing to disclose them.

PRAYER FOR RELIEF

HRG requests that this Court:

A. Declare that the FDA's withholding of the requested records is unlawful;

B. Order the FDA to make the requested records available to HRG at no cost and without delay;

C. Award HRG its costs and reasonable attorneys' fees under 5 U.S.C. § 552(a)(4)(E); and

D. Grant all other appropriate relief.

Dated: January 27, 2020

Respectfully submitted,

/s/ Patrick D. Llewellyn
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