UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KREMERS URBAN PHARMACEUTICALS INC.,
1011 C Avenue West
Seymour, IN 47274

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue, Silver Spring, MD 20993

Defendant.

Civil Action No. _____

On October 17, 2016, the United States Food and Drug Administration (FDA) issued Kremers Urban Pharmaceuticals, Inc. (Kremers) a General Advice Letter and a "Proposal to Withdraw Approval of an Abbreviated New Drug Application for Extended-Release Methlyphenidate Tablets; Notice of Opportunity for Hearing"—published in the Federal Register on October 18, 2016 (*see* 81 Federal Register 71741-71745)—proposing to withdraw approval of Kremers' abbreviated new drug application (ANDA) 091695.[1] By statute, FDA must provide Kremers "due notice and an opportunity for hearing" before withdrawing approval of ANDA 091695. 21 U.S.C. § 355(e). Kremers must have access to evidence to support its position in those proceedings.

Accordingly, Kremers sent two FOIA requests in November 2016 related to FDA's proposal. On January 10, 2017, Kremers filed a separate litigation about those requests, and that litigation remains pending. *See Kremers Urban Pharmaceuticals Inc., v. United States Food and Drug Admin.*, 1:17-cv-50-RCL, (D.D.C.). On August 8, 2017, Kremers sent a third FOIA request to FDA asking for additional documents and information and requesting expedited processing. Without that information, Kremers will be hamstrung in its ability to support its request for a

[1] Lannett Company, Inc. acquired Kremers in November 2015.

hearing and to prepare for any hearing. The information requested is also important to the public understanding of the agency's review process.

To date, FDA has failed to produce the requested records and failed to claim an exemption from disclosure. The Court should order FDA to produce the requested records.

PARTIES

1. Kremers Urban Pharmaceuticals Inc. is an Indiana corporation with its principal place of business at 1101 C Avenue West, Seymour, Indiana 47274. Lannett Company Inc. acquired Kremers in November 2015.

2. FDA is an agency within the meaning of 5 U.S.C. § 552(f)(1) that has possession, custody, and control of records that Kremers seeks under FOIA. FDA's principal address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. FDA's Division of Freedom of Information is located at 5630 Fishers Lane, Room 135, Rockville, Maryland 20857.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action under 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

4. Venue is proper in this Court under 28 U.S.C. § 1391(e) and 5 U.S.C. § 552(a)(4)(B) because FDA is an agency of the United States Government and because the FOIA statute provides for jurisdiction and venue in the District of Columbia over all FOIA actions.

5. Because FDA failed to make a determination and provide notice of that determination within the statutorily mandated time limit of twenty working days after receiving Kremers' August 8, 2017 FOIA request, Kremers is deemed to have exhausted all its administrative remedies under 5 U.S.C. § 552(a)(6)(C). *See* 5 U.S.C. § 552(a)(6)(A)(i).

BACKGROUND

6. FOIA "focuses on the citizens' right to be informed about what their government is up to" by requiring the release of "[o]fficial information that sheds light on an agency's performance of its statutory duties." *Dep't. of Justice v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 750, 773 (1989). "[D]isclosure, not secrecy, is the dominant objective."

Dep't. of Interior v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8 (2001) (internal quotation marks omitted).

7. The Supreme Court has often noted "the Act's goal of broad disclosure," insisting that FOIA's "exemptions be given a narrow compass." *Milner v. Dep't of Navy*, 562 U.S. 562, 571 (2011).

KREMERS' FOIA REQUEST

8. On August 8, 2017, Kremers, through its counsel Alston & Bird, made a FOIA request to FDA asking for various records relating to developments in the industry that occurred after Kremers' November 2016 FOIA requests. Additional requests also arose from Kremers' review of information provided to it after the date of those requests. Kremers asked for expedited processing. A copy of that FOIA request is attached as Exhibit 1.

9. On August 9, 2017, FDA acknowledged receipt of Kremers' August 8, 2017 request. On August 16, 2017, FDA denied Kremers' request for expedited processing.

10. To date, FDA has not produced the records requested through the August 8, 2017 FOIA request, said that it would produce any particular requested document, or claimed any exemption from disclosure.

11. Because FDA failed to communicate its "determination" on the FOIA request within twenty working days (5 U.S.C. § 552(a)(6)(A)), Kremers has constructively exhausted its administrative remedies and may proceed directly to this Court. *See Citizens for Responsibility & Ethics in Washington v. Fed. Election Comm'n*, 711 F.3d 180, 186 (D.C. Cir. 2013) (a FOIA requestor exhausts its administrative remedies unless, within the specified period, the agency "inform[s] 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"); *id.* at 189 ("[I]f the agency does not adhere to FOIA's explicit timelines, the 'penalty' is that the agency cannot rely on the administrative exhaustion requirement to keep cases from getting into court.").

12. No "exceptional circumstances" justify giving FDA additional time to respond to Kremers' FOIA requests. 5 U.S.C. § 552(a)(6)(C)(ii). If anything, FDA should be required to

produce the records as soon as possible because they may support Kremers' position in the ANDA proceedings.

COUNT I: VIOLATION OF FOIA (5 U.S.C. § 552)

13. Kremers incorporates all previous allegations (including those from the introduction to the Complaint).

14. FDA is unlawfully withholding records that Kremers requested under 5 U.S.C. § 552.

15. FDA's failure to disclose the requested records has injured Kremers and will continue to do so until the agency discloses the records.

PRAYER FOR RELIEF

Kremers requests the following relief:

1. Expedited consideration;

2. A declaratory judgment that FDA has improperly withheld the requested records under FOIA;

3. A finding that FDA's failure to comply with its obligations under FOIA has harmed Kremers;

4. An order directing FDA to respond and produce the requested documents on an expedited basis;

5. Costs and reasonable attorneys' fees under 5 U.S.C. § 552(a)(4)(E); and

6. Any other relief that the Court deems appropriate.

Date: September 27, 2017.

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