EXHIBIT 1

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November 7, 2016

BY FACSIMILE (301) 827-9267 AND OVERNIGHT MAIL

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FOIA Request for **Expedited Processing**
(Docket No. FDA-2016-N-3120)

To Whom It May Concern:

We represent the Lannett Company, Inc. (Lannett) and its newly acquired affiliate Kremers Urban Pharmaceuticals Inc. This is a request for information under the Freedom of Information Act (FOIA), 5 U.S.C. §552, and FDA's implementing regulations (21 CFR Part 20). We request **expedited processing** and delivery of the requested documents.

On October 18, 2016, FDA issued a Notice of Opportunity for Hearing (*see* 81 Federal Register 71741-71745 (October 18, 2016)) proposing to withdraw approval of Kremer's abbreviated new drug application (ANDA) 091695 (*see* copy attached). In accordance with 21 U.S.C. §355(e), §12.1 *et seq.*, and §314.200, Kremers will request a hearing to challenge the proposed application withdrawal no later than November 17, 2016. By December 19, 2016, Kremers must provide FDA with all data, information, and analyses supporting the Company's request for a hearing. If that information is insufficient, the agency may withdraw approval of the ANDA without granting Kremers a hearing.

By statute, FDA must provide "due notice and an opportunity for hearing" to Kremers before withdrawing approval of ANDA 091695. §355(e). In that regard, §355(e) codifies what the Constitution always requires: due process. As part of the required "due notice," FDA must provide Kremers with the information that the agency relied on to issue the Notice of Opportunity for Hearing. Without complete information, Kremers will not

have a constitutionally adequate opportunity to support its request for a hearing or to prepare for any hearing. Given the shortness of time, **we request expedited processing.** Our client will lose substantial due process rights if it does not receive the requested essential documents in time to use them as it prepares its case against withdrawal of ANDA 091695 (Methylphenidate ER Tablets). *See Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 616 (D.C. Cir. 1976), *citing* 5 U.S.C. §552(a)(6)(c)(some FOIA requests necessarily involve a far greater degree of urgency than others and that when a requester can show "exceptional need or urgency," the request should be processed on an expedited basis.)

We request copies of the following materials which, in the interest of time, may be **provided to us on a rolling or staggered basis** as they are obtained and reviewed:

(1) Adverse event reports and FDA summary reports from December 2012 - present for Mallinckrodt's generic, Kremers' generic, Concerta, and the authorized generic (Watson/Actavis).

a. Nearly 200 complaints for the Mallinckrodt product and more than 100 complaints for the Kremers product (May 2013 to June 2014).[1]

b. The 340 reports citing lack of effect (February 2014 to May 2015).[2]

c. Adverse Events Report Analysis comparing Kremers' product with the authorized generic including the therapeutic failure rates.[3]

d. Adverse event reports and FDA summary reports citing lack of effect (May 2015 to present).

e. Sales/prescription information and calculation that FDA used to determine the therapeutic failure rate per 100,000 person-years corresponding to a given number of complaints.

(2) Complaints received from "other sources" for ANDAs 091695 and 202608 (e.g., FDA Detroit District Office, Author Gina Pera's Website, and Dr.

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[1] *See* FDA, "Questions and Answers Regarding Methylphenidate Hydrochloride Extended Release Tablets (generic Concerta) made by Mallinckrodt and UCB/Kremers Urban (formerly Kudco)" ("FDA Q&A"), at Question #8, *available at* http://www.fda.gov/drugs/drugsafety/ucm422569 (last visited Nov. 1, 2016).

[2] John Peters, "Memorandum in Support of Beginning Approval Withdrawal Proceedings for ANDA 091695" ("Withdrawal Memo") (Oct. 1, 2016), at pp. 6-7.

[3] 81 Fed. Reg. 71741 (Oct. 18, 2016), at 71743.

Renee Roberts, Director of Anesthesia Support Services at the Children's National Medical Center, Washington, D.C).[4]

(3) Data or complaint reports to support the positive dechallenge and positive rechallenge statements.[5]

(4) FDA's laboratory testing methods, data, and reports for the comparative analysis of the drug design, composition, stability, dissolution, and active pharmaceutical ingredient (API) degradation of Kremers' product compared to Concerta.[6]

(5) Bioequivalence (BE) Data review and outlier analysis reports for Kremers' product versus Concerta.[7]

(6) Post-Tracked Safety Issue (TSI) Investigation BE data reanalysis report.[8]

(7) FDA's Post-TSI Investigation pharmacokinetic ("PK") modeling/simulation report.[9]

(8) Report for Modeling of potential clinical impact of the Mallinckrodt generic done as part of the TSI investigation.[10]

(9) Meeting minutes and reports of the "broad interdisciplinary consultation with FDA physicians, pharmacists, chemists, and other agency scientists and experts."[11]

(10) Protocol and report (with data) from FDA sponsored BE study initiated in October 2014 for Mallinckrodt's product[12] or similar data run on Kremers' product.

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[4] 81 Fed. Reg. at 71743, n.2; John R. Peters, "Memorandum: Tracked Safety Issue (TSI) #1349 – Methylphenidate ER Summary and Conclusions to ANDA 091695" ("TSI Memo") (Oct. 30, 2014), at p. 4.

[5] Withdrawal Memo, at p. 7.

[6] FDA Q&A, Question #8; 81 Fed. Reg. at 71743; TSI Memo, at p. 5.

[7] 81 Fed. Reg. at 71743; TSI Memo, at p. 6.

[8] 81 Fed. Reg. at 71744.

[9] Withdrawal Memo, at pp. 9-10; 81 Fed. Reg. at 71744; TSI Memo at pp. 7-10.

[10] 81 Fed. Reg. 71737 (Oct. 18, 2016), at 71739.

[11] FDA Q&A, at Question #8.

[12] FDA Q&A, at Question #12; 81 Fed. Reg. at 71740.

(11) FDA's clinical study protocol for its PK and pharmacodynamic (PD) study in children with ADHD initiated October 2014 (expected completion date: September 2017)[13] or similar protocol initiated for Kremers' product.

(12) Concerta and authorized generic clinical data that assures compliance with the November 2014 BE guidance.[14]

(13) FDA's review of the individual BE analysis of the 2015 pivotal fasting and fed studies submitted to FDA by Kremers.[15]

(14) Reports, meeting minutes, data analyses, public comments, and other material surrounding and supporting the development of FDA's November 2014 BE guidance for Concerta.[16]

(15) Reports, meeting minutes, data analyses, public comments, and other materials documenting how FDA evaluated the magnitude of the nocebo effect and/or adjusted for it in FDA's analysis of complaint data for Kremers' generic product compared to Concerta and the authorized generic.

(16) Any PK/PD modeling done to determine the impact of Concerta's food effect on safety/efficacy (SKAMP scores), along with confidence intervals or other evidence that the results were statistically significant.

(17) Any PK/PD modeling done to evaluate Kremers' assertion that its fed state PK profile was nearly superimposable with the Concerta fasting PK profile, along with confidence intervals or other evidence that the results were statistically significant.

(18) Meeting minutes, correspondence, emails, or other material documenting FDA discussions, rationale, and/or justifications leading up to the issuance of the latest letters to Kremers.

(19) Any documents or information relating to an earlier request (FOIA or otherwise) for any of the items listed above.

This request is for records wherever they are held at FDA, although it is possible that the records described above are easiest to locate at FDA's Northeast laboratory in

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[13] FDA Q&A, at Question #12.

[14] FDA "Draft Guidance on Methylphenidate Hydrochloride" Revised 2014.

[15] Kremers "0047; General Coorspondence-Information Request per FDA Meeting held on July 20, 2015" for ANDA 091695, July 27, 2015.

[16] Supra at Note 14.

Jamaica, New York, FDA's Philadelphia District Office, or FDA headquarters in Maryland.

Please forward all materials responsive to this request to me at the following address: Alston & Bird LLP, 950 F Street, NW, Washington, DC 20004. As noted, **we request expedited processing** under 5 U.S.C. §552(a). Unless Kremers receives the requested materials soon, it will not have an adequate opportunity to support its request for a hearing (i.e., Kremers' supporting materials are due by December 19, 2016), or to prepare adequately for any hearing if granted. As §552(a) contemplates, we expect to receive a response within 10 working days to our request for expedited processing (i.e., no later than November 21, 2016).

In the interest of time, we would appreciate your providing this information on a rolling basis as documents become available. If you conclude that a document responsive to this request contains material or information that falls within the statutory exemptions to mandatory disclosure, we request that you review that material or information for possible discretionary disclosure and, in any event, produce all reasonably segregable portions of the material or information. In that regard, the Executive Order issued by President Obama in 2009 establishes a presumption favoring disclosure. *See* 74 Fed. Reg. 4683 (Jan. 26, 2009) ("All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open Government. The presumption of disclosure should be applied to all decisions involving FOIA."). Even more recently, the Supreme Court emphasized FOIA's "goal of broad disclosure." *Milner v. Dep't of Navy*, 562 U.S. 562, 565 (2011).

If for any reason you decide to withhold (e.g., not produce) a document or a portion of a document, we request that the agency promptly notify me of its decision, explaining all the legal and factual bases for any decision to deny disclosure.

Inasmuch as agency regulations require us to pay reasonable fees for the processing of this request, we are willing to do so. But we request that you notify me beforehand if the fees to be incurred in responding to this request will exceed $1,000.

Thank you for your assistance. We appreciate your beginning to produce the documents requested as soon as possible and on a rolling basis as appropriate. If you have any questions regarding this request, please call me at 202-239-3465, or contact me at marc.scheineson@alston.com.

Sincerely,

Marc J. Scheineson

enclosure
cc: Ms. Maryll W. Toufanian (maryll.toufanian@fda.hhs.gov)