EXHIBIT 2

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November 18, 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: Additional 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 additional 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 under the rationale contained in our prior FOIA Request dated November 7, 2016.

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) Information including data, reports, studies, internal and external communications, or any other records related to FDA's review and assessment of the bioequivalence of Kremers Urban's ANDA for Methylphenidate ER (091695) except those that are provided to us in response to other FOIA questions filed previously.

(2) Any PK/PD modeling comparing the Kremers and Concerta products in the fed state including but not limited to the statistical significance, if any, of the Kremers-Concerta differences in PD effect.

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).

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)