DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 15, 2019

Philip J. Perry
Latham & Watkins, LLP
555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requests to take the following actions:

1. Rescind its acceptance for filing of Lannett's 505(b)(2) application if Lannett did not complete the QT, renal, hepatic, leachable, and/or other studies deemed necessary for an NDA for a cocaine hydrochloride product to be sufficiently complete to permit substantive review; and refuse to file any reapplication by Lannett of its application until the expiration of the NCE exclusivity attached to NDA 209963.

2. Rescind its acceptance for filing of Lannett's 505(b)(2) application that was resubmitted in response to FDA's CRL because such a submission is prohibited by FDA's regulation on duplicate 505(b)(2) filings, and permit Lannett to resubmit its application only as an ANDA after the expiration of the NCE exclusivity attached to NDA 209963.

Your submission was received by this office on 08/14/2019. It was assigned docket number FDA-2019-P-3855. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby

Digitally signed by Dynna Bigby
Date: 2019.08.16 12:05:48 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management Staff
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