DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 4, 2019

Michael J. Freno
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Seattle,WA 98104-1158

Sent via email to: *michael.freno@klgates.com*

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner refuse to accept any submissions by Lannett Company, Inc. ("Lannett") in furtherance of its application submitted under the 21 U.S.C. § 355(b)(2) approval pathway (a "505(b)(2)") for cocaine hydrochloride, 4% and 10%. Any such submissions by Lannett are barred by the new chemical entity exclusivity arising from FDA's approval of Genus's new drug application ("NDA") 209963 under Section 505(c)(3)(E)(ii) of the FDCA was received by this office on 2/1/2019.

It was assigned docket number FDA-2019-P-0538. 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2019.02.04 16:15:45 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)