



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 12, 2019

Kurt R. Karst
Hyman, Phelps & McNamara P.C
700 Thirteenth Street, NW Suite 1200
Washington, D.C. 20005-5929

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate ANDA 084285 (Dicyclomine Hydrochloride Capsules, 10 mg) held by Lannett Co Inc (or another appropriate ANDA) as a RS for purposes of FDA evaluation of ANDAs for Dicyclomine Hydrochloride Capsules, 10 mg was received by this office on 08/12/2019.

It was assigned docket number FDA-2019-P-3800. 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
Supervisory Administrative Proceedings Specialist
Division of Dockets Management Staff
FDA/Office of Operations (OO)