DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 18, 2019

Patti Smith
IQVIA RDS Inc.
4820 Emperor Blvd-4th Floor
Durham, NC 27703

Sent via email to: patti.smith@iqvia.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate an additional reference standard for Dicyclomine Hydrochloride Capsules in the Approved Drug Products with Therapeutic Equivalence Evaluations since the current reference standard is not available in the market was received by this office on 12/17/2019.

It was assigned docket number FDA-2019-P-5970. 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: 2019.12.18 11:44:29 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)