DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 7, 2020

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Sent via email to: drosen@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA designate ALCAINE (Proparacaine Hydrochloride) Ophthalmic Solution 0.5%, ANDA # A080027 held by Alcon Laboratories Inc. as an additional Reference Standard to enable applicants to conduct the comparative studies needed to develop the generic version of Ophthaine (Proparacaine Hydrochloride) Ophthalmic Solution, 0.5% NDA # N008883 held by Apothecon Inc Div Bristol Myers Squibb for ANDA submission was received by this office on 04/06/2020.

It was assigned docket number FDA-2020-P-1260. 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: 2020.04.07 09:59:17 -04'00'

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