David L. Rosen, B.S. Pharm., JD
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Washington Harbour
3000 K Street, N.W., Suite 600
Washington, DC 20007-5143

October 1, 2020

Re: Docket No. FDA-2020-P-1260

Dear Mr. Rosen:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 6, 2020. Your petition requests that FDA designate Alcaine (proparacaine hydrochloride) ophthalmic solution 0.5%, abbreviated new drug application (ANDA) 080027, 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% new drug application 008883, held by Apothecon Inc Div Bristol Myers Squibb for ANDA submission.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Date: 2020.10.01 09:52:12 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research