Kris Tucker
Bausch+Lomb
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807

June 24, 2024

Re: Docket No. FDA-2024-P-0109

Dear Petitioner:

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 January 4, 2024. Your petition requests that the Agency

- Refuse to receive or approve any ANDA relying on Xipere as the RLD if that ANDA uses a different injector unless that submission includes *in vivo* and switching studies demonstrating the safety and efficacy of the product;
- Revise its recent draft PSG to require the same; and
- Revise the recent draft PSG to include syringeability and glide force as physicochemical characteristics required for comparative purposes.

(Petition at 2.)

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 Date: 2024.06.24 09:34:47 -04'00'

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