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August 30, 2022

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305) Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Request to Withdraw Citizen Petition, Docket No. FDA-2022-P-1965

Dear Sir or Madam:

The undersigned ("Petitioner") requests withdrawal of its Citizen Petition filed on August 19, 2022 (Docket No. FDA-2022-P-1965) as moot. Prior to consideration of the petition FDA issued a determination that Xylocaine® (Lidocaine Hydrochloride) Jelly 2%, approved under New Drug Application ("NDA") number 008816 was not discontinued or withdrawn for safety or effectiveness reasons. (refer to the attached screen shot from the Orange Book in **Attachment 1**). Petitioner requests withdrawal of its petition without prejudice under 21 C.F.R. § 10.30(g).

If you have any questions or require additional information, please contact the undersigned.

Respectfully submitted,

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Attachment 1: Electronic Edition of the Orange Book showing the determination that Xylocaine® (lidocaine hydrochloride) Jelly 2% approved under NDA No. 008816 was not discontinued or withdrawn for safety or effectiveness reasons.