August 22, 2022

Sherry L. Rollo
Hahn Loeser & Parks LLP
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Chicago, IL 60606

Sent via email to: srollo@hahnlaw.com

Dear Petitioner:

Your submission requesting that the Commissioner promptly determine whether Xylocaine® (Lidocaine Hydrochloride) Jelly 2%, approved under New Drug Application ("NDA") number 008816, held by Akorn Operating Co. LLC, has been voluntarily withdrawn or discontinued from sale for reasons of safety or effectiveness and requests that the FDA declare that is appropriate to submit an Abbreviated New Drug Application ("ANDA") for Xylocaine® (Lidocaine Hydrochloride) Jelly 2% that relies on an RLD that is no longer marketed was received and processed under CFR 10.30 by this office on 08/19/2022.

It was assigned docket number FDA-2022-P-1965. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.08.22 12:36:16 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)