FOLEY & LARDNER LLP

FOLEY & LARDNER LLP
ATTORNEYS AT LAW
WASHINGTON HARBOUR
3000 K STREET, N.W., SUITE 600
WASHINGTON, D.C. 20007-5143
202.672.5300 TEL
202.672.5399 FAX
www.foley.com
WRITER'S DIRECT LINE
202.672.5430
drosen@foley.com EMAIL

April 6, 2020

VIA ELECTRONIC SUBMISSION

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

ANDA SUITABILITY PETITION

Dear Sir / Madam:

The undersigned (the "Petitioner") submits this ANDA Suitability Petition under the provisions of section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR § 314.93 to request that the Food and Drug Administration ("FDA") determine that the proposed drug product, Lidocaine Hydrochloride Injection, USP, 20 mg/2 mL (10 mg/mL), 2 mL Fill vials is suitable for submission in an Abbreviated New Drug Application ("ANDA") as discussed below.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs allow the submission of an ANDA for Lidocaine Hydrochloride Injection USP, 20mg /2mL (10mg/mL), 2 mL Fill vials (total vial content 20mg) pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR § 314.93. Currently Lidocaine HCl Injection USP, 1% Multiple Dose Vial, is available as 200 mg per 20mL (10 mg/mL) and 500 mg per 50mL (10 mg/mL) vials from Fresenius Kabi USA, LLC and is sold under the brand name Xylocaine® (NDA # N006488) which is also the Reference Listed Drug (RLD). The total amount of drug per vial of 20 mL is 200mg and for 50mL is 500 mg.

As per the RLD label Approval dated 12/22/2017 of FRESENIUS KABI USA LLC, 10 mL fill (100 mg per 10 ml) Multiple dose vial was also available under How supplied section provided as **Attachment 1**.

The proposed change in the vial size 2 mL (total amount of drug per vial is 20 mg) is the type of change that has been expressly authorized in the statute and by FDA regulations. The Agency has approved other ANDA with similar type of change in vial size. Further discussion is provided below. Draft labeling is enclosed with this Suitability Petition.

B. Statement of Grounds

1. As noted above, Lidocaine Hydrochloride Injection USP, 20mg/mL, is approved in 10 ml, 20 mL and 50 mL vial (total amount of drug per vial is 100 mg, 200mg and 500 mg respectively) from Fresenius Kabi USA, LLC and is sold under the brand name Xylocaine®. Xylocaine® (Lidocaine HCl Injection USP), (10mg/mL) 1% Multiple Dose Vial, 10 ml, 20mL and 50 mL vials, are approved by FDA under NDA 006488 is designated as the reference listed drug ("RLD") in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the purpose of serving as the RLD for generic products. **Attachment 2** includes a copy of the record for NDA 006488 from the current electronic edition of the Orange Book.

2. The proposed product, for Lidocaine Hydrochloride Injection USP, (10 mg/mL) 1% Multiple Dose Vial 2 mL Fill, is quantitatively and qualitatively the same as the RLD.

   A chart comparing the formulations of the RLD and the proposed drug is presented below:

Ingredient	Xylocaine®- RLD	Proposed Drug
Lidocaine Hydrochloride USP	10mg/mL	10mg/mL
Sodium Chloride, USP to adjust tonicity	7mg/mL	7mg/mL
Methylparaben	1mg/mL	1mg/mL
Sodium Hydroxide to adjust pH	As needed	As needed
Hydrochloric Acid to adjust pH	As needed	As needed
Water for Injection	QS	QS

3. The company will be seeking a waiver of *in vivo* bioavailability requirements under 21 CFR 320.22 (b)(1).

4. The proposed change in vial size (a change in the total amount of drug per vial) is the type of change that has been expressly authorized in the statute and by FDA regulation. In the past, the Agency has approved numerous ANDA for similar types of changes.

5. The INDICATIONS AND USAGE is the same for both the RLD and the proposed drug, as follows:

   Xylocaine (lidocaine HCl) Injections are indicated for production of local or regional anesthesia by infiltration techniques such as percutaneous injection and intravenous regional anesthesia by peripheral nerve block techniques such as brachial plexus and intercostal and by central neural techniques such as lumbar and caudal epidural blocks, when the accepted procedures for these techniques as described in standard textbooks are observed. The most current labeling for the RLD is included as **Attachment 3**. Draft Labeling for proposed product is included as **Attachment 4**.

6. Section 505(j)(2)(C) of the FDCA directs FDA to approve a petition requesting a change from a listed drug as suitable for evaluation under an ANDA unless FDA finds that investigations must be conducted to show the safety and effectiveness of the drug or Any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug. For the purposes of that section of the FDCA, the proposed drug differs from the RLD only in strength - that is, the fill volume of the vial used to package the drug. The Petitioner does not believe that investigations are necessary to evaluate the safety and effectiveness of the proposed drug product because: (1) the identity and concentration of the active ingredients (lidocaine hydrochloride) is identical to those of the RLD and thus are currently approved as safe and effective[1] (2) the proposed strength i.e. fill volume (2 mL fill) is the same as per other approved ANDAs listed in below mentioned table.

Strength	**Proposed Drug Product** Lidocaine Hydrochloride Injection, USP multiple dose vial	**Reference Listed Drug** Xylocaine ® (Lidocaine HCl Injection, USP) multiple dose vial	**Other Generic Drug Product** Lidocaine Hydrochloride Injection, USP multiple dose vial
1%	2 mL Vial	**Currently not Marketing** **RLD label is not reflecting the 2 mL Pack*/@**	Available in ANDA No.# (A088586) label of FRESENIUS KABI USA under prescription marketing status as per Drugs@FDA and FDA Orange book.
			Available in ANDA No.# (A080407) label of WEST-WARD PHARMS INT with Discontinued marketing status as per Orange book and Drugs@FDA website.

*As per the current approved label dated 11/02/2018 of FRESENIUS KABI USA LLC 2 mL & 10 mL fill Multiple dose vial is not currently mentioned in how supplied section.

@ As per the label Approval dated 12/22/2017 of FRESENIUS KABI USA LLC 10 mL fill Multiple dose vial was available under How supplied section.

[1]The same ingredients and their concentrations are also currently approved under Fresenius Kabi USA, LLC's ANDA 088586 and West Ward Pharmaceuticals ANDA 080407

7. Pediatric Research Equity Act (FD&C Act section 505(B)(b))
   The Pediatric Research Equity Act requires that applications be evaluated for safety and efficacy in pediatric populations when the submission is for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. The proposed petition does not seek any such changes to the RLD; therefore, the petitioner believes that it is not necessary to seek a waiver or deferral for pediatric studies.

For the foregoing reasons, the Petitioner respectfully requests that the Commissioner to approve this Petition and find that an ANDA for the proposed product Lidocaine Hydrochloride Injection USP, (10 mg/mL) 1% Multiple Dose Vial 2 mL Fill is suitable for submission.

C. ENVIRONMENTAL IMPACT STATEMENT

The Petitioner requests a categorical exclusion from the requirement to prepare an environmental assessment under 21 C.F.R. § 25 .31(a). To the best of Petitioner's knowledge, no extraordinary circumstances exist that would warrant the preparation of an environmental assessment.

D. ECONOMIC IMPACT STATEMENT

As provided in 21 CFR §10.30(b), the Petitioner agrees to submit economic impact information if requested by the Commissioner of Food and Drugs following review of the Petition.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

David L. Rosen, B.S. Pharm., JD