September 16, 2020

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

CITIZEN PETITION

Dear Sir/Madam,

The undersigned ('petitioner') submits this Citizen Petition electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.25(a), 10.30 and 314.93, to request the Food and Drug Administration to **designate a suitable alternative reference standard (RS**) for purpose of developing the proposed generic drug product and conducting bioequivalence studies to support our ANDA application for Lidocaine Hydrochloride Jelly 2% with reference to the current Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

The request is being made on the following grounds;

1. The current Orange Book lists "**XYLOCAINE** (lidocaine hydrochloride) Jelly 2% (NDA # 008816)" of Oak Pharmaceuticals Inc. as the Reference Listed Drug/Reference Standard (RS). However, though not listed as discontinued in electronic Orange Book, as per IMS (MAT) data quantity of the current reference standard is not available or so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for development and bioequivalence testing. The non-availability statement of samples from the distributor indicate that the current designated reference standard samples are unavailable.

2. Approved generic product, "Lidocaine Hydrochloride Jelly 2% (**ANDA # 040433**) of Akron Inc." listed in the Orange Book, is currently the highest marketed drug product and hence, eligible to be designated as Reference Standard due to limited or non-availability of the current Orange Book listed reference standard "XYLOCAINE (lidocaine hydrochloride) Jelly 2% (NDA # 008816)" of Oak Pharmaceuticals Inc.

A. Action Requested

Aurolife Pharma LLC requests the Food and Drug Administration (FDA) to designate the approved "Lidocaine Hydrochloride Jelly 2% (**ANDA # 040433**) of Akron Inc.", as a new Reference Standard, upon which ANDA applicant can rely for purpose of development and bioequivalence testing required for ANDA filing.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as Abbreviated New Drug Applications (ANDA's) in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (The Orange Book).

FDC Act §505(j) allows the marketing of generic versions of previously approved drug products when the generic drug product is the subject of an ANDA. To obtain ANDA approval, the application sponsor must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product has the same active ingredient(s) in the same strength, has essentially identical labeling.

Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book) database current through September 2020* is provided in following table;

Market Status	**RX**	**RX**	**RX**	**RX**
Active Ingredient	Lidocaine Hydrochloride	Lidocaine Hydrochloride	Lidocaine Hydrochloride	Lidocaine Hydrochloride
Proprietary Name	Xylocaine	Lidocaine Hydrochloride	Lidocaine Hydrochloride	Glydo
Application No.	**N008816**	**A040433**	**A086283**	**A201094**
Product Number	001	001	001	001
Dosage Form / Route	Jelly; Topical	Jelly; Topical	Jelly; Topical	Jelly; Topical
Strength	2%	2%	2%	2%
TE Code	AT	AT	AT	AT
RLD	**RLD**	No	No	No
RS	**RS**	No	No	No
Applicant Holder	Oak Pharmaceuticals Inc.	Akron Inc.	International Medication System	Sagent Pharmaceuticals Inc.
Approval Date	Prior to Jan 1, 1982	Feb 12, 2003	Prior to Jan 1, 1982	Apr 28, 2014

* Data accessed on September 16, 2020.

Other approved ANDAs (# A080429, A081318 and A040837) of Lidocaine hydrochloride Jelly are listed in the discontinued section of the orange Book.

Due to market unavailability of designated reference standard in enough quantity, evaluation/comparison of Aurolife Pharma LLC's generic drug could not be executed.

As per Draft Guidance for Industry, ***Referencing Approved Drug Products in ANDA Submissions, Ill. C.2 and 3***,

"FDA also will consider selecting a new reference standard when the Agency determines that the quantity of the current reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing (even if the current reference standard is not in the Discontinued Section of the Orange Book). When selecting a new reference standard, FDA generally selects a drug product that is therapeutically equivalent to the discontinued RLD and is the market leader based on units sold."

"If there is a reference standard in the Active Section of the Orange Book but there are limited or no quantities of the reference standard in distribution, or a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, then the potential applicant may submit a citizen petition under 21 CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference standard."

The Petitioner (Aurolife Pharma LLC) therefore requests FDA to designate one of the approved generic products and preferably "Lidocaine Hydrochloride Jelly 2% (**ANDA # 040433**) of Akron Inc." as a new Reference Standard (RS) considering it appears to lead the U.S. market in terms of number of units sold (as per IMS data) and should therefore be more readily accessible and more appropriate for RS designation.

In support of the designation of the reference standard to Approved Generic Product "Lidocaine Hydrochloride Jelly 2% (**ANDA # 040433**) of Akron Inc.", we have included the following data:

1. Current Orange Book Search Result
2. NDC Directory Search Result
3. Drugs@FDA Search Result
4. Detailed IMS, Moving Annual Total (MAT) data indicating Approved Generic product "Lidocaine Hydrochloride Jelly 2% (ANDA # 040433) of Akron Inc.", as the leading player in the U.S market.
5. Non availability of samples statement from pharmacy/distributors.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. 25.31(a) and 25.15(d).

D. Economic Impact Statement

Pursuant to 21 C.F.R. 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. This information will be promptly provided, if so requested.

E. Certification

The undersigned (petitioner) 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 is unfavorable to this petition.

Sincerely yours,

Blessy Johns

Digitally signed by Blessy Johns
DN: c=US, st=New Jersey, l=Dayton, o=Aurobindo Pharma USA, Inc., cn=Blessy Johns, email=bjohns@aurobindousa.com
Date: 2020.09.16 14:16:40 -04'00'

Blessy Johns
Director Regulatory Affairs
Aurolife Pharma LLC
(Subsidiary of Aurobindo Pharma USA, Inc.)

Contact details:
Aurobindo Pharma USA, Inc.,
279 Princeton-Hightstown Road,
East Windsor, NJ 08520, USA,
Tel: 732-839-4380; Cell: 908-240-1822
Fax No.:732- 355-9940
E-mail: bjohns@aurobindousa.com

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	LIDOCAINE HYDROCHLORIDE	GLYDO	A201094	JELLY	TOPICAL	2%	AT			SAGENT PHARMACEUTICALS INC
RX	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	A040433	JELLY	TOPICAL	2%	AT			AKORN INC
RX	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	A086283	JELLY	TOPICAL	2%	AT			INTERNATIONAL MEDICATION SYSTEM
RX	LIDOCAINE HYDROCHLORIDE	XYLOCAINE	N008816	JELLY	TOPICAL	2%	AT	RLD	RS	OAK PHARMACEUTICALS INC
DISCN	LIDOCAINE HYDROCHLORIDE	ANESTACON	A080429	JELLY	TOPICAL	2%				BIONPHARMA INC
DISCN	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	A081318	JELLY	TOPICAL	2%				COSETTE PHARMACEUTICALS INC
DISCN	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	A040837	JELLY	TOPICAL	2%				WATSON LABORATORIES INC

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
Lidocaine	17478-711-31	20 mg/mL	JELLY	TOPICAL	ANDA040433	Akorn, Inc.	17478-711	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2003	N/A	ANDA
Lidocaine	17478-711-10	20 mg/mL	JELLY	TOPICAL	ANDA040433	Akorn, Inc.	17478-711	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2003	N/A	ANDA
Lidocaine	17478-711-30	20 mg/mL	JELLY	TOPICAL	ANDA040433	Akorn, Inc.	17478-711	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2003	N/A	ANDA
Lidocaine	17478-811-10	20 mg/mL	JELLY	TOPICAL	ANDA040433	Akorn, Inc.	17478-811	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2003	N/A	ANDA
Lidocaine	17478-811-30	20 mg/mL	JELLY	TOPICAL	ANDA040433	Akorn, Inc.	17478-811	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2003	N/A	ANDA
Lidocaine	17478-840-05	20 mg/mL	JELLY	TOPICAL	ANDA040433	Akorn, Inc.	17478-840	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2013	N/A	ANDA
Lidocaine	17478-840-30	20 mg/mL	JELLY	TOPICAL	ANDA040433	Akorn, Inc.	17478-840	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2013	N/A	ANDA
Lidocaine	50090-0555-0	20 mg/mL	JELLY	TOPICAL	ANDA040433	A-S Medication Solutions	50090-0555	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/01/2003	N/A	ANDA
Sx1 Medicated Post-Operative System	70529-941-01		KIT		ANDA040433	IT3 Medical LLC	70529-941	Lidocaine Hydrochloride		HUMAN PRESCRIPTION DRUG	05/01/2016	N/A	ANDA
Venipuncture Px1	70529-254-01		KIT		ANDA040433	IT3 Medical LLC	70529-254	Lidocaine Hydrochloride		HUMAN PRESCRIPTION DRUG	05/01/2016	N/A	ANDA

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Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
Xylocaine	76478-479-05	20 mg/mL	JELLY	TOPICAL	NDA008816	Oak Pharmaceuticals, Inc. (Subsidiary of Akorn, Inc.)	76478-479	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2012	N/A	NDA
Xylocaine	76478-479-30	20 mg/mL	JELLY	TOPICAL	NDA008816	Oak Pharmaceuticals, Inc. (Subsidiary of Akorn, Inc.)	76478-479	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	07/01/2012	N/A	NDA

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Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 008816
Company: OAK PHARMS

Products on NDA 008816

Approval Date(s) and History, Letters, Labels, Reviews for NDA 008816

Labels for NDA 008816

Therapeutic Equivalents for NDA 008816

XYLOCAINE

JELLY;TOPICAL; 2%
TE Code = AT

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	
GLYDO	LIDOCAINE HYDROCHLORIDE	2%	JELLY;TOPICAL	Prescription	No	AT	201094 (I event=ov
LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	2%	JELLY;TOPICAL	Prescription	No	AT	040433 (I event=ov
LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE	2%	JELLY;TOPICAL	Prescription	No	AT	086283 (I event=ov

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	
XYLOCAINE	LIDOCAINE HYDROCHLORIDE	2%	JELLY;TOPICAL	Prescription	Yes	AT	008816