

September 24, 2020

**VIA ELECTRONIC SUBMISSION**

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

**CITIZEN PETITION**

Dear Sir or Madam:

The undersigned submits this Citizen Petition pursuant to the Federal Food, Drug and Cosmetic Act (“FDC Act”) and in accordance with 21 C.F.R. §§ 10.25(a) and 10.30 to request that FDA amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) to designate Lidocaine Hydrochloride Topical Jelly, 2%, approved under Abbreviated New Drug Application (“ANDA”) 040433, as a new Reference Standard (“RS”).

**I. ACTION REQUESTED**

The undersigned requests that FDA designate ANDA 040433 listed in the Orange Book for Lidocaine Hydrochloride Topical Jelly, 2%, as a RS for purposes of submitting an ANDA for a generic version of the drug product.

**II. STATEMENT OF GROUNDS**

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 applicant 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, dosage form and route of administration, has essentially identical labeling, and is bioequivalent.

A “listed drug” includes a new drug product that has an effective approval under FDC Act § 505(j), that has not been withdrawn or suspended under FDC Act §§ 505(e)(1) through (5) or (j)(5), and that has not been withdrawn from sale for reasons of safety or effectiveness. See 21

C.F.R. § 314.3. Listed drugs are identified in FDA’s Orange Book. An RLD is the listed drug identified by FDA as the drug product on which an ANDA applicant should rely in seeking approval of an application.

A “reference standard,” designated as “RS” in the Orange Book, is the product that an ANDA applicant must use to conduct in vivo bioequivalence testing required for approval. Generally, FDA selects a single RS, which is the same as the RLD. FDA may select a new RS to further the submission and evaluation of generic drug applications. In determining whether to select a new RS, FDA will consider the marketing status of the RLD, the impact a new RS could have on preventing shortages, and the quantity of the current RS in distribution. *See* FDA, *Draft Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions*, at 8-9 (Jan. 2017). FDA will typically select as a new RS a drug product that is therapeutically equivalent to the RLD and the market leader. FDA may also consider other factors that may “make the development process more efficient.” *Id.* at 9.

A potential ANDA applicant may request that FDA select a new RS when another may be more appropriate (e.g., where there is “limited or no quantities of the reference standard in distribution”), or if there is no RS in the “Active Section” of the Orange Book. Requests for changes to FDA’s selection of the RS because the applicant believes another RS is more appropriate requires the submission of a citizen petition to request that FDA select a different listed drug as a new RS. *See id.* at 9.

There is a sound basis for selecting Akorn Inc.’s Lidocaine Hydrochloride Topical Jelly, 2%, approved under ANDA 040433 as a new RS. The current RS (and RLD), XYLOCAINE (lidocaine hydrochloride) Topical Jelly, 2%, approved under NDA 008816 and having Oak Pharmaceuticals Inc. (a subsidiary of Akorn Inc.) as the Applicant Holder, is reportedly not available for purchase (and may no longer be marketed) in the United States (see **Attachment 1** for letters from PBI and Castle Hill Pharmaceutical Distributors confirming that Xylocaine Topical Jelly, 2%, by Oak Pharmaceuticals, is not available for sale and Akorn generic drug product is available in market). This effectively prevents further generic competition. In an effort to introduce further competition, FDA should designate Lidocaine Hydrochloride Topical Jelly, 2%, approved under ANDA 040433, as a new RS. We have been assured that Lidocaine Hydrochloride Topical Jelly, 2%, held by Akorn Inc. under ANDA 040433, is readily accessible. Furthermore, based on information (Source: IQVIA), Akorn Inc.’s Lidocaine Hydrochloride Topical Jelly, 2%, approved under ANDA 040433 is the market leader for this Product. It is therefore a suitable candidate for RS designation.

Accordingly, the undersigned requests that FDA designate Akorn Inc.’s Lidocaine Hydrochloride Topical Jelly, 2%, approved under ANDA 040433 as a new RS in the Orange Book.

### III. ENVIRONMENTAL IMPACT

An environmental assessment report on the action requested in this petition is not required under 21 C.F.R. § 25.31.

#### **IV. ECONOMIC IMPACT**

In accordance with 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. Petitioner hereby commits to promptly provide this information, if so requested.

#### **V. 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 is unfavorable to the petition.

Sincerely,

Michelle R. Ryder  
Principal Consultant  
Lachman Consulting Services, Inc.

# ATTACHMENT 1



PHARMACEUTICAL BUYERS, INC.

YOUR BEST SOURCE FOR U.S. AND GLOBAL  
CLINICAL SUPPLIES/INNOVATOR SAMPLES  
CONTROLLED SUBSTANCES

July 9, 2020

Dear Malavika,

The item XYLOCAINE 2% - NDC# 76478-479-30 by Oak Pharma is not listed with any of our suppliers.

Kindest regards,

A handwritten signature in blue ink, appearing to read 'RK', is positioned below the text 'Kindest regards,'.

Ross Korval  
Pharmaceutical Buyers Inc.  
Ph# 516-437-4500  
Fax# 516-437-3600





# **CASTLE HILL PHARMACEUTICAL DISTRIBUTORS**

**706 CASTLE HILL AVENUE, BRONX, NY 10473**

**718-319-8200, Fax: 718-319-8240**

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Date: 7/9/2020

## **To Whomsoever it may concern**

Xylocaine 2% Jelly 30mL with NDC#76478-0479-30 is not available with our sources but we have access to authorized generic Lidocaine HCL 2% Jelly 30mL with NDC#17478-0711-30 and Lidocaine HCL 2% jelly 10x5mL with NDC#17478-0711-31, by Akorn. Above mentioned NDC's are the only available authorized generic in Market at this moment.

Best Regards,

  
Hemant Desai, RPh





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**718-319-8200, Fax: 718-319-8240**

Date: 7/9/2020

**To Whomsoever it may concern**

Casporyn HC otic suspension 10mL with NDC#70199-0011-10 is not available in market at this moment.

Best Regards,

A handwritten signature in black ink, appearing to read 'Hemant', written over a diagonal line.

Hemant Desai, RPh