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September 23, 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 Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension/Drops, approved under Abbreviated New Drug Application ("ANDA") 062488, as a new Reference Standard ("RS").

I. ACTION REQUESTED

The undersigned requests that FDA designate ANDA 062488 listed in the Orange Book for Neomycin and Polymyxin B Sulfates and Hydrocortisone (Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate) Otic Suspension/Drops, 1%; Eq. 3.5 MG Base/mL; 10,000 units/mL, 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A "listed drug" includes a new drug product that has an effective approval under FDC Act § 505(j), that has not been withdrawn or suspended under FDC Act §§ 505(e)(1) through (5) or

(j)(5), and that has not been withdrawn from sale for reasons of safety or effectiveness.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 Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension/Drops approved under ANDA 064065 as a new RS. The current RS (and RLD), CASPORYN HC (Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate) Otic Suspension/Drops, 1%; Eq. 3.5 MG Base/mL; 10,000 units/mL, approved under NDA 060613, is reportedly not available for purchase (and may no longer be marketed) in the United States (see **Attachment 1** for letter from PBI confirming Casporyn RLD is not available for sale). This effectively prevents further generic competition. In an effort to introduce further competition, FDA should designate Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension/Drops, 1%; Eq. 3.5 MG Base/mL; 10,000 units/mL, approved under ANDA 06465, as a new RS. ANDA 06465, marketed by Bausch &Lomb., is the market leader based on units sold of the currently approved ANDAs for RLD CASPORYN HC (Hydrocortisone; Neomycin Sulfate; Polymyxin B Sulfate) Otic Suspension/Drops. It is therefore a suitable candidate for RS designation. Accordingly, the undersigned requests that FDA designate in the Orange Book drug product approved under ANDA 06465 as a new RS.

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

Michelle R. Ryder
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2020.09.23 07:22:11 -06'00'

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

ATTACHMENT 1

PBI

PHARMACEUTICAL BUYERS, INC.

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

July 8, 2020

Dear Malavika,

The item CASPORYN by Casper Pharma is not listed with any of our suppliers.

Kindest regards,

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