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September 3, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
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 hereby submits this Citizen Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), and 21 C.F.R. § 314.93, and in accordance with 21 C.F.R. § 10.25(a) and 21 C.F.R. § 10.30, to request that the Food and Drug Administration ("FDA") amend the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") to designate different listed drug also as a reference standard.

A. Action Requested

The Petitioner hereby requests that the Commissioner of Food and Drugs designate OTICAIR Otic Suspension USP, ANDA # A064065 held by BAUSCH AND LOMB PHARMACEUTICALS INC. as a Reference Standard to permits its use by an ANDA applicant for conducting the comparative studies needed to develop the generic version of CASPORYN HC Otic Suspension (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP) 1%; EQ 3.5MG BASE/ML; 10,000 Units/mL, NDA # N060613 held by CASPER PHARMA LLC.

B. Statement of Grounds

Based on the Section III.C.3 "Requesting Selection of a Reference Standard" in the "*Draft Guidance for Industry – Reference Approved Drug Products in ANDA Submissions*", issued by FDA in January 2017, a potential applicant "may submit a citizen petition under 21CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference

standard". The requirement for a potential applicant to submit a Citizen Petition, according to the above-mentioned Guidance is that "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".

For the case of CASPORYN HC Otic Suspension (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP) 1%; EQ 3.5MG BASE/ML; 10,000 Units/mL, as shown in the Orange Book from FDA website current through August 2020, the RLD and RS was assigned by FDA to the product with the NDA number N060613, with the current applicant holder identified as CASPER PHARMA LLC.

A copy of the FDA's Approved Drug Products with Therapeutic Equivalency Evaluation (FDA's Orange Book) is included as an **Attachment 1**.

Our client is developing an ANDA for this product and needs the RLD/RS to conduct comparative studies. However, beginning in March 2020, my client has been informed by the RLD/RS wholesale drug suppliers that CASPORYN HC Otic Suspension (neomycin and polymyxin B sulfates and hydrocortisone otic suspension, USP) 1%; EQ 3.5MG BASE/ML; 10,000 Units/mL held by CASPER PHARMA LLC is on backorder and not available in the US market.

Due to unavailability of RLD/RS product in the US market, the Petitioner believes that it meets the condition that "there are limited or no quantities of the reference standard in distribution", as mentioned as one of the conditions for allowing petition of adding a new RS for the product in the FDA Guidance.

As the latest information that our client has, currently wholesale suppliers are distributing the Oticair Otic Suspension USP, 1%; EQ 3.5MG BASE/ML; 10,000 Units/mL (ANDA # A064065) held by BAUSCH AND LOMB PHARMACEUTICALS INC in the US market.

Based on above, the Petitioner respectfully requests FDA to designate additional "RS" status to Oticair Otic Suspension USP, 1%; EQ 3.5MG BASE/ML; 10,000 Units/mL (ANDA # A064065) held by BAUSCH AND LOMB PHARMACEUTICALS INC.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR § 25.31.

D. Economic Impact Statement

Pursuant to 21 CFR § 10.30(b), we do not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

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 that are unfavorable to the petition.

Respectfully submitted,

David L. Rosen, BS Pharm., JD

Enclosure:

Attachment 1

Copy of the relevant pages from Approved Drug Products with Therapeutic Equivalence Evaluations, Electronic Orange Book.