**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 3, 2020

David L. Rosen, BS Pharm., JD
FOLEY & LARDNER LLP
3000 K STREET, N.W., Suite 500
Washington, D.C. 20007-5143

Sent via email to: drosen@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA 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 was received by this office on 09/03/2020.

It was assigned docket number FDA-2020-P-1849. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.09.03 15:59:30 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)