DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 6, 2022

Anthony LaViola, M.S., RAC, Principal Consultant
Pharmobedient Consulting, LLC
642 N.E. 3rd Ave.
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Sent via email to: anthonv@pharmobedient.com

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug Administration to determine and declare that Diclofenac Potassium Orally Disintegrating Tablets (ODT), 25 mg and 50 mg is suitable for submission in an Abbreviated New Drug Application (ANDA) was received and processed under CFR 10.30 by this office on 01/06/2022.

It was assigned docket number FDA-2022-P-0052. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-Bigby

Digitally signed by Dynna Gorham-Bigby
Date: 2022.01.06 14:28:54 -05'00'

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