December 6, 2022

Frederik Defesche
Regcon Solutions
12555 High Bluff Dr #130
San Diego, CA 92130

Sent via email to: fdefesche@regconsolutions.com

Dear Petitioner:

Your submission requesting that the Commissioner to declare that the drug product Moxifloxacin hydrochloride ophthalmic solution/drops 0.5%-unit dose (0.4 mL fill volume) is suitable for consideration in an abbreviated new drug application (ANDA) was received and processed under CFR 10.30 by this office on 11/30/2022.

It was assigned docket number FDA-2022-P-3046. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, 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,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.12.06 16:31:20 -05'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)