November 30, 2022

**Submitted Electronically**

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**SUITABILITY PETITION**

Dear Sir or Madam:

The undersigned submits this Suitability Petition electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 10.20 and 10.30, to request the Commissioner of the Food and Drug Administration 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).

## A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Moxifloxacin hydrochloride ophthalmic solution/drops 0.5%-unit dose (0.4 mL fill volume) is suitable for submission as an ANDA. The reference listed drug product (RLD), upon which this petition is based, is Vigamox® (Moxifloxacin hydrochloride) ophthalmic solution/drops 0.5% multidose (3 mL fill in a 4 mL bottle), New Drug Application ("NDA") 021598 currently held by Novartis Pharmaceuticals Corporation (“Novartis”), as designated in the Orange Book (see copy of the page from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations [i.e., Orange Book, (Attachment 1)]. Therefore, the petitioner seeks a change in strength (from multidose with a 3 mL fill volume to unit dose with a 0.4 mL fill volume) from that of the listed drug product. The composition of the product would be Qualitatively and Quantitatively (Q1/Q2) identical to the RLD.

## B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The RLD, Vigamox® (Moxifloxacin hydrochloride) ophthalmic solution/drops by Novartis is an ophthalmic solution containing 0.5% moxifloxacin with a 3 mL fill volume presented as a multi-

dose product. The proposed drug product is also an ophthalmic solution containing 0.5% moxifloxacin, but it is unit-dose with a 0.4 mL fill volume. This petition is thus seeking a change in fill volume from multidose with a 3 mL fill volume to unit dose with a 0.4 mL fill volume.

The proposed change in strength represents a dosage strength that is consistent with the dosing recommendations of the RLD's approved labeling. The current dosing instructions in the approved labeling of the RLD states, "Instill one drop in the affected eye 3 times a day for 7 days "The proposed unit dose formulation will contain suitable solution for administering the recommended dose of one drop in the affected eye.

There are no proposed changes in labeling except for the change in fill volume and addition of a statement to discard the single-use vial after use sought in this petition. The uses, indications, warnings, and directions for use will remain the same as that of the RLD. Draft labeling for the proposed product is included in Attachment 3, and the RLD's approved labeling is provided in Attachment 2.

Therefore, the petitioner's request for the Commissioner to find that a change in fill volume from a 3 mL fill volume to a 0.4 mL fill volume should raise no questions of safety or effectiveness, and the Agency should approve the petition.

## C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25 .31.

## D. Economic Impact Statement

Pursuant to 21 C.F.R. § 10.30(b), the Petitioner will, upon request by the Commissioner, submit economic impact information.

## E. Certification

The undersigned certifies that to the best of its knowledge, this petition includes all information on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the petition.

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Attachment:

1. Excerpt from FDA's Orange Book
2. Approved Labeling for Reference Listed Drug
3. Draft insert labeling for Proposed Product