Date: July 29, 2022

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
FDA's Division of Dockets Management
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

SUITABILITY PETITION

Dear Sir or Madam:

The undersigned petitioner submits this petition under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FD&C Act"), and in accordance with 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30 requesting the Commissioner of the Food and Drug Administration ("FDA") to declare that the proposed drug product, posaconazole for delayed-release oral suspension, USP, 100 mg is suitable for consideration in an Abbreviated New Drug Application ("ANDA").

A. ACTION REQUESTED

The petitioner requests that the Commissioner of the FDA declare that the proposed drug product posaconazole for delayed-release oral suspension, USP, 100 mg is suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based, is NOXAFIL® (posaconazole) delayed-release tablets, for oral use, 100 mg, held by MERCK SHARP AND DOHME CORP, NDA 205053.

Therefore, the petitioner requests a change from the RLD, MERCK SHARP AND DOHME CORP's NOXAFIL® (posaconazole) delayed-release tablets, for oral use, only in its dosage form (from delayed-release tablets to delayed-release oral suspension).

B.STATEMENT OF GROUNDS

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a drug product that differs in dosage form from that of the listed drug, provided the FDA has approved a petition that proposed filing such an application. The most recent interne listing of the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) lists the RLD as Application Number N205053, approved Nov 25, 2013 as Prescription, MERCK SHARP AND DOHME CORP, NOXAFIL, delayed-release tablets. The proposed drug product is an orally

delayed-release form of the suspension, is the same strength as the RLD. The proposed product contains the same active ingredient as the RLD and is intended to the same route of administration. Thus, the proposed product will be labeled with the same conditions of use as the listed drug and is expected to have the same therapeutic effect when used as indicated in the labeling.

A copy of the RLD labeling is included in Attachment 1. The labeling of the proposed product is expected to be the same as that for the RLD, with the exception of the section denoting the manufacturer, and the change in dosage form and dosing method, which will instruct the user to mixture the drug by some amount of water. A copy of the draft proposed package data is provided in Attachment 2.

According to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drug and Biological Products in Pediatric Patents; Final Rule (Pediatric Final Rule) 63 FR 66632 published December 2, 1998, and the waiver requirements set forth in 21 CFR § 314.55(c).

The petitioner is also requesting a waiver of the requirement to conduct pediatric studies in accordance with the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drug and Biological Products in Pediatric Patents; Final Rule (Pediatric Final Rule) 63 FR 66632 published December 2, 1998, and the waiver requirements set forth in 21 CFR § 314.55(c).

PREA authorizes the FDA to waive the requirement to submit the pediatric assessment, based on established criteria, for some of all pediatric age groups. Applicant request the waiver based on the following data:

1. The data comes from the label of NOXAFIL: Clinical Trial Experience in Pediatric Patients (2 to less than 18 Years of Age). The safety of Noxafil injection and Noxafil PowderMix for delayed-release oral suspension for prophylaxis of invasive fungal infections has been assessed in an open label uncontrolled dose-ranging PK and safety study (Noxafil injection/ Noxafil PowderMix for delayed-release oral suspension Pediatric Study 1, NCT02452034); hereinafter referred to as Noxafil Pediatric Study) in 115 immunocompromised pediatric patients 2 to less than 18 years of age with known or expected neutropenia. Noxafil injection and Noxafil PowderMix for delayed-release oral suspension was administered at daily doses of up to 6 mg/kg (twice daily on day 1) in three dose cohorts. All 115 subjects initially received Noxafil injection for at least 7 days, and 63 subjects were transitioned to Noxafil PowderMix for delayed-release oral suspension. The mean overall treatment duration for all treated subjects was 20.6 days with 14.3 days (range: 1 to 28 days) on Noxafil injection and 11.6 days (range: 2 to 18 days) on Noxafil PowderMix for delayed-release oral suspension.

2. The formulation of NOXAFIL® (posaconazole) delayed-release tablets include posaconazole, croscarmellose sodium, hydroxypropylcellulose, hypromellose acetate succinate, iron oxide yellow, Macrogol/PEG 3350,

magnesium stearate, microcrystalline cellulose, polyvinyl alcohol paially hydrolyzed, silicon dioxide, talc, and titanium dioxide.

The formulation of the proposed drug product include posaconazole, HPMCAS, mannitol, microcrystalline cellulose and carboxymethylcellulose sodium, xanthan gum, anhydrous citric acid, sodium citrate, saccharin sodium, colloidal silicon dioxide, flavor. The formulation of the proposed drug product is safe for children who can take the proposed posaconazole for delayed-release oral suspension.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR § 25.31.

D. Economic Impact

The petitioner does 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 if includes representative data and information known to the petitioner, which are unfavorable to the petition.

During the course of the review of this application, if there are any questions or comments, please do not hesitate to contact us via telephone at +86-18364375017 or e-mail: wangying@hqdds.com.

Respectfully submitted,

Huang Jingshan

Vice President

Reyoung Pharmaceutical Co., Ltd.

Attachment 1: Current labeling for NOXAFIL® (posaconazole) delayed-release tablets, for oral use, 100 mg, held by MERCK SHARP AND DOHME CORP, NDA 205053. (Revised: 1/2022, source: Drugs@FDA)

Attachment 2: Draft Package Insert Proposed for posaconazole for delayed-release oral suspension, USP, 100 mg.

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