Date: May 18, 2022

Division of Dockets Management

Department of Health and Human Services

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

The undersigned, ApicHope Pharmaceutical (USA) Limited submits this petition under 21 CFR 10.25(a) and 10.30 to request the Food and Drug Administration (FDA) to determine whether the Reference Standard (RS) of CEFDINIR powder for suspension (125 mg/5 mL; 250 mg/5 mL) manufactured by Sandoz approved under the Abbreviated New Drug Application (ANDA) 065337, was discontinued or withdrawn for safety or effectiveness reasons.

A. Action Requested

The petitioner requests that FDA determine whether RS CEFDINIR powder for suspension (125 mg/5 mL; 250 mg/5 mL) approved under ANDA 065337 was discontinued or withdrawn for safety or effectiveness reasons and to designate an additional RS.

B. Statement of Grounds

Under the FD&C Act, an ANDA must rely on FDA's approval findings for a Reference Listed Drug ("RLD"). See FD&C Act § 505(j) (2). If the listed drug has ceased to be offered from sale by its manufacturer, a person wishing to submit Abbreviated NDA ("ANDA") for the drug must petitioned FDA for a determination of whether the drug was withdrawn. See 21 C.F.R §§ 314.122 and 314.161. If FDA determines that the listed drug was discontinued or withdrawn for safety or effectiveness reasons, then the drug listing is removed from the Orange Book. See i.d. § 314.161.

If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the listing remains in the Orange Book and may be cited in an ANDA as RLD. The regulations also provide that the Agency must make a determination as to whether a listed drug is

withdrawn from sale for safety and/or effectiveness reasons before an ANDA that refers to that listed drug may be approved (see 21 CFR 314.161(a)(l)).

The Orange Book currently identifies CEFDINIR powder for suspension (125 mg/5 mL; 250 mg/5 mL) approved by the FDA on April 6, 2007, under ANDA 065337 by Sandoz, is the RS. However, CEFDINIR powder for suspension (125 mg/5 mL;250 mg/5 mL) was not available for sale and listed in FDA shortage database (Attachment 1). The petitioner is not aware of any information indicating that the discontinuation was made for safety or effectiveness and believes that the discontinuation of CEFDINIR powder for suspension under ANDA 065337 was due only to commercial considerations.

As per the guidance "Referencing Approved drug products in ANDA submissions" Section III.B.2 wherein if an RLD appears in the Discontinued Section and FDA has not yet made a determination whether the drug was withdrawn from sale for reasons of safety or effectiveness, the applicant must submit a citizen petition under 21 CFR 10.25(a) and 10.30 at the same time as the ANDA submission, seeking a determination whether the listed drug has been withdrawn from sale for safety or effectiveness reasons.

As Sandoz's RS CEFDINIR powder for suspension (125 mg/5 mL;250 mg/5 mL) continues to be listed in FDA drug shortages database at the time of submission of this petition, the petitioner requests that FDA determine whether CEFDINIR powder for suspension (125 mg/5 mL;250 mg/5 mL) is discontinued or withdrawn for safety or effectiveness reasons.

If Sandoz reintroduces CEFDINIR powder for suspension (125 mg/5 mL; 250 mg/5 mL) to the commercial market after submission of this petition and prior to FDA's response, the petitioner will at such time request the withdrawal of this 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

Pursuant to 21 CFR § 10.30(b), upon request by the Commissioner, the Petitioner will, submit an

economic impact information.

E. Certification

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

Sincerely,

Signature: Lin Lu

Lu Lin, Ph.D.

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