March 10, 2020

[BY ELECTRONIC SUBMISSION]

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

The undersigned respectfully submits this citizen petition on behalf of Yiling Pharmaceutical Ltd (Yiling) under 21 CFR 10.25(a) and 10.30, to request that the Commissioner of Food and Drug Administration (the Commissioner) determine whether a listed drug has been withdrawn for safety or effectiveness reasons as outline below.

A. Action Requested

The petition requests that the Commissioner of the Food and Drug Administration determine whether ZOVIRAX® (acyclovir) Oral Capsule 200 mg (Mylan Pharmaceuticals Inc.), NDA 018828, has been voluntarily withdrawn from sale for safety or efficacy reasons.

B. Factual Background

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications (ANDAs). This list, referred to as the Orange Book, is divided into three sections: (1) approved prescription drug products; (2) approved over-the-counter drug products; and (3) discontinued drug products. ZOVIRAX® (acyclovir) Oral Capsule 200 mg (Mylan Pharmaceuticals Inc.), NDA 018828, was approved by the FDA on Jan 25, 1985. However, ZOVIRAX® (acyclovir) Oral Capsule 200 mg is currently listed in the discontinued section of the Orange Book. A copy of the Orange Book listing ZOVIRAX® oral capsule 200 mg is provided as Attachment 1. The Petitioner is unaware of the precise date when ZOVIRAX® oral capsule 200 mg was removed from the approved prescription drug product section to the discontinued drug product section of the Orange Book. The Petitioner believes that Mylan has discontinued marketing the drug product for commercial reasons.

Under FDA regulations, drugs are withdrawn from the market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 C.F.R. § 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 § C.F.R. 314.161(a)(1)).

It should be emphasized, at the time of this petition's submission, there is no

evidence that Mylan is marketing ZOVIRAX® (acyclovir) Oral Capsule 200 mg. Accordingly, Petitioner respectfully requests that FDA determine whether ZOVIRAX® (acyclovir) Oral Capsule 200 mg was discontinued for reasons of safety or efficacy reasons, in order to enable action on an ANDA referring to ZOVIRAX (acyclovir) Oral Capsule 200 mg as the Reference Listed Drug. Should the NDA holder recommence marketing ZOVIRAX® (acyclovir) Oral Capsule 200 mg after the submission of this petition and prior to an FDA response, and there is evidence that the product is available in the marketplace, the Petitioner will consider this petition moot. The Petitioner will at that time take the appropriate action to request withdrawal of the petition.

C. Environmental Impact

The actions requested in this petition are subject to categorical exclusion under 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

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 it includes representative data and information known to the petitioner which are unfavorable to the petition.

_____(Signature)

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