U.S. FOOD & DRUG ADMINISTRATION

Kwok Hang Wu
Yiling Pharmaceutical LTD
5348 Vegas Drive
Las Vegas, Nevada 89108

July 2, 2020

Re: Docket No. FDA-2020-P-1072

Dear Mr. Wu:

This letter responds to your citizen petition received on March 10, 2020, requesting that the Food and Drug Administration (FDA) determine whether ZOVIRAX (acyclovir) Oral Capsule 200 mg, approved under new drug application 018828, held by Mylan Pharmaceuticals Inc., was withdrawn from sale for safety of efficacy reasons (Petition at 1).

FDA has reviewed its records and determined that ZOVIRAX, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain ZOVIRAX (acyclovir) Oral Capsule 200, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-9120.

Sincerely,

Jessica G. Tierney -S

Digitally signed by Jessica G. Tierney -S
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Date: 2020.07.02 08:01:36 -04'00'

Jessica Tierney
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure