



Terry G. Mahn  
Fish & Richardson P.C.  
1000 Maine Avenue, S.W.  
Suite 1000  
Washington, DC 20024

August 8, 2022

Re: Docket No. FDA-2022-P-0594

Dear Mr. Mahn:

This letter responds to your petition for stay of action received on April 14, 2022 (Petition), requesting that the Food and Drug Administration (FDA) stay the effective date of its April 8, 2022, final approval of abbreviated new drug application (ANDA) 214082, “until expiration of the [Federal Food, Drug, and Cosmetic Act] 30-month statutory stay that has been in effect and is not due to expire until August 3, 2022” (Petition at 1).

The time frame for which you requested FDA stay the final approval of ANDA 214082 has passed. Therefore, we dismiss the Petition as moot.

Sincerely,

Douglas C.  
Throckmorton -S

Digitally signed by Douglas  
C. Throckmorton -S  
Date: 2022.08.08 13:17:37  
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Patrizia Cavazzoni, M.D.  
Director  
Center for Drug Evaluation and Research