



April 14, 2022

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Sent via email to: [mahn@fr.com](mailto:mahn@fr.com)

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug to stay the effective date of its April 08, 2022, final approval of ANDA No. 214082, until expiration of the FDCA 30-month statutory stay that has been in effect and is not due to expire until August 3, 2022 was received and processed under CFR 10.30 & 10.35 by this office on 04/14/2022.

It was assigned docket number FDA-2022-P-0594. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the stay of action petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)