April 6, 2022

Jeremy R. Jessen, General Counsel, Vice President, Consumer Health
Bayer U.S. LLC
Law, Patents & Compliance
100 Bayer Boulevard
Whippany, NJ 07981

Sent via email to: jeremy.jessen@bayer.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug confirm that FDA will stay the final approval of ANDA 216421 until the expiration of the 30-month period beginning on the date when Bayer received the notice described in FDCA § 505(j)(2)(B) (i.e., the paragraph IV notice) of the submission of ANDA 216421 with a certification described in FDCA § 505(j)(2)(A)(vii)(IV) (i.e., a paragraph IV certification), absent any event specified in FDCA § 505(j)(5)(B)(iii) that would cause the stay to be shortened, lengthened, or terminated was received and processed under CFR 10.30 & 10.35 by this office on 04/05/2022.

It was assigned docket number FDA-2022-P-0536. 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.04.07 11:57:35 -04'00'

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

cc: (esharkey@cov.com)