



**Suitability Petition  
Completeness Assessment Correspondence**

Hyman, Phelps & McNamara, P.C.  
700 13th Street, N.W., Suite 1200  
Washington, DC 20005  
Attn: Kurt Karst

Sent via email to: KKarst@hpm.com

Docket No. FDA-2024-P-0545

Dear Kurt Karst:

This is in reference to your petition received on January 29, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission, in accordance with 21 C.F.R. §314.93(b), to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Buspirone Hydrochloride Oral Solution, 2 mg/mL. The petition was examined for initial completeness (i.e. Completeness Assessment) under CFR 10.30 and the Agency has made a threshold determination that the petition is complete.

This petition is subject to the provisions of the Generic Drugs User Fee Amendments of 2022 (GDUFA III) whereby any suitability petitions submitted in FY 2024-2027 will receive a goal date of 6 months after the completeness assessment. The GDUFA goal date for review of this petition is August 6, 2024.

If you have any questions, contact [ANDAFiling@fda.hhs.gov](mailto:ANDAFiling@fda.hhs.gov).

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

*{See appended electronic signature page}*

Elizabeth Kim, MSN, APRN, FNP-BC  
Regulatory Officer  
Division of Filing Review  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Elizabeth  
Kim

Digitally signed by Elizabeth Kim

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