



August 18, 2022

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*Sent via email to:* [drosen@foley.com](mailto:drosen@foley.com)

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug determine that an Abbreviated New Drug Application may be submitted for Busulfan Injection, USP 5 mg/mL was received and processed under CFR 10.30 by this office on 08/18/2022.

It was assigned docket number FDA-2022-P-1940. Please refer to this docket number in future correspondence on this subject with the Agency.

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

Sincerely,

Karen Malvin  
Acting Director  
Dockets Management Staff  
FDA/Office of Operations (OO)