EXHIBIT B

John R. Manthei
john.manthei@lw.com

555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: +1.202.637.2200 Fax: +1.202.637.2201
www.lw.com

LATHAM & WATKINS LLP

May 16, 2019

EXPEDITED TREATMENT REQUESTED

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Freedom of Information Act Request

To Whom It May Concern:

Pursuant to the federal Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, Latham & Watkins LLP ("Latham") requests copies of the records described below, as well as expedited processing of this request. If Latham's request is denied in whole or in part, please justify all denials by reference to specific exemptions under FOIA. Please also release all segregable portions of otherwise exempt material. Latham will pay all necessary fees. Specifically, this letter requests:

1. All records associated with the Investigational New Drug Application ("IND") and New Drug Application ("NDA") 209321, including the original NDA submission and all amendments, submitted by Jacobus Pharmaceutical Company, Inc. for Ruzurgi (amifampridine), including, but not limited to, formal and informal correspondence with the Food and Drug Administration ("FDA"); meeting requests, briefing materials, meeting minutes; and the review package, including approval letters, labeling, and application review files (e.g., summary review(s), clinical pharmacology and biopharmaceutics review(s), medical review(s), chemistry review(s), statistical review(s), non-clinical review(s), risk assessment and risk mitigation review(s), proprietary name review(s), other review(s), administrative documents and correspondence, etc.).

2. All records associated with the IND and NDA 208078, including the original NDA submission and all amendments, submitted by Catalyst Pharmaceuticals, Inc. for Firdapse (amifampridine phosphate), including, but not limited to, formal and informal correspondence with the FDA; meeting requests, briefing materials, meeting minutes; and the review package, including approval letters, labeling, and application review files (e.g., summary review(s), clinical pharmacology and biopharmaceutics review(s),

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medical review(s), chemistry review(s), statistical review(s), non-clinical review(s), risk assessment and risk mitigation review(s), proprietary name review(s), other review(s), administrative documents and correspondence, etc.).

I would appreciate communication by email or telephone, rather than postal mail. Please feel free to contact me directly with any questions at 202.637.2211 or john.manthei@lw.com. Thank you for your assistance.

Best regards,

John Manthei /MG

John R. Manthei
of LATHAM & WATKINS LLP