IND 169429

GRANT FAST TRACK

NeuroRx, Inc.
Attention: M. Daniel Gordin, PhD
Regulatory Affairs
913 North Mark Street, Suite 200
Wilmington, DE 10020

Dear Dr. Gordin:

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for NRX-101 (D-cycloserine and lurasidone) capsule (fixed dose combination).

We also refer to your November 14, 2023, request for Fast Track designation. We have reviewed your request and concluded that it meets the criteria for the Fast Track designation. Therefore, we are designating as a Fast Track development program the investigation of NRX-101 (D-cycloserine and lurasidone) capsule (fixed dose combination) for the treatment of complicated urinary tract infections (cUTI) including acute pyelonephritis. Please note that if the clinical development program you pursue does not continue to meet the criteria for Fast Track designation, the application will not be reviewed under the Fast Track program.

For further information regarding Fast Track Drug Development Programs, please refer to the guidance for industry *Expedited Programs for Serious Conditions – Drugs and Biologics*.[1] This document may be requested from the Office of Communications, Division of Drug Information at 301-796-3400 or 1-888-463-6332.

We remind you that under section 561A(f)(2) of the FD&C Act (§21 U.S.C. 360bbb-0) you are required to make your expanded access policy for NRX-101 (D-cycloserine and lurasidone) capsule (fixed dose combination) publicly available within 15 days of the signature date of this letter. For further information regarding how to make your expanded access policy publicly available, you may visit our expanded access webpage on FDA.gov.[2]

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[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] https://www.fda.gov/news-events/expanded-access/expanded-access-information-industry#IndustryRole

If you have any questions, contact Eva Zuffova, Regulatory Project Manager, at (301) 796-0697.

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PETER W KIM
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