DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 129194

GRANT FAST TRACK

NeuroRx, Inc.
Attention: Jonathan C. Javitt, MD, MPH
913 North Market Street, Suite 200
Wilmington, DE 19801

Dear Dr. Javitt:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for NRX-100 (ketamine IV infusion) and NRX-101 (fixed dose combination of D-cycloserine and lurasidone) sequential therapy.

We also refer to your June 13, 2017, 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-100 (ketamine IV infusion) followed by NRX-101 (fixed dose combination of D-cycloserine and lurasidone) for induction and maintenance of remission from acute suicidal ideation and behavior in patients with bipolar depression. 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 FDA document "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.

[1] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf

If you have any questions, contact Danbi Lee, Regulatory Project Manager, at danbi.lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, MD
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
08/10/2017