IND 169429

GRANT QUALIFIED INFECTIOUS DISEASE PRODUCT DESIGNATION

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 (FDCA) for NRX-101 (D-cycloserine and lurasidone) capsule (fixed dose combination).

We also refer to your request for Qualified Infectious Disease Product (QIDP) designation, received on November 14, 2023, for your NRX-101 (D-cycloserine and lurasidone) capsule (fixed dose combination) for oral use. We have reviewed your request and conclude that it meets the criteria for QIDP designation for the requested indication. Therefore, we are designating your NRX-101 (D-cycloserine and lurasidone) capsule (fixed dose combination) for oral use as a QIDP for the following indication:

- Treatment of complicated urinary tract infections (cUTI) including acute pyelonephritis

Please note that QIDP designation applies to a specific drug or biologic product from a specific sponsor, and for a specific use for which it is being studied. Therefore, if, during development, there are significant changes to any of these criteria, a new request for a QIDP designation should be submitted. For additional information, refer to Questions 2 and 5 of the Guidance for Industry: Qualified Infectious Disease Product Designation: Questions and Answers (May 2021).

If you have any questions, contact Eva Zuffova, Regulatory Health 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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