



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 112621

GRANT FAST TRACK

Neurelis, Inc.
c/o Pacific Link Consulting, LLC
Attention: Richard Lowenthal, MS, MSEL
President, Pacific-Link Consulting
8195 Run of the Knolls Court
San Diego, CA 92127

Dear Mr. Lowenthal:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for NRL-1 (diazepam intranasal solution).

We also refer to your October 31, 2016, request for Fast Track designation. We have reviewed your request and concluded that it meets the criteria for Fast Track designation. Therefore, we are designating as a Fast Track development program the investigation of NRL-1 for the management of selected, refractory patients with epilepsy, on stable regimens of AEDs, who require intermittent use of diazepam to control bouts of increased seizures. 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 E. Andrew Papanastasiou, Regulatory Project Manager, via email at emilios.papanastasiou@fda.hhs.gov or by phone at (301) 796-1930.

Sincerely,

{See appended electronic signature page}

Billy Dunn, MD
Director
Division of Neurology 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/

WILLIAM H Dunn
12/27/2016