



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"<sup>1</sup>. This document may be requested from the Office of Communications, Division of Drug Information at 301-796-3400 or 1-888-463-6332.

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<sup>1</sup> <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](mailto: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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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WILLIAM H Dunn  
12/27/2016