DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209321/Original 2

TENTATIVE APPROVAL

Jacobus Pharmaceutical Company, Inc.
Attention: Laura R. Jacobus
Vice President & Director of Quality Assurance
37 Cleveland Lane, P.O. Box 5290
Princeton, NJ 08540

Dear Ms. Jacobus:

Please refer to your New Drug Application (NDA) dated June 15, 2018, received June 15, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ruzurgi (amifampridine), 10 mg tablets.

We acknowledge receipt of your major amendment dated January 7, 2019, which extended the goal date by three months.

(b) (4)

For administrative purposes, we have designated the following:

- NDA 209321/Original 1 (Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age)
- NDA 209321/Original 2 (b) (4)

The subject of this action letter is NDA 209321/Original 2. A separate action letter will be issued for NDA 209321/Original 1.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling text. This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The Orphan Drug provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 360aa-360dd, provide for a grant of seven years of market exclusivity to which a period of pediatric exclusivity may attach. Orphan drug exclusivity blocks approval of any other application for the same drug for the same indication. Due to the orphan exclusivity granted to

Catalyst Pharmaceuticals, Inc., for Firdapse, your application for Ruzurgi may not be finally approved for marketing under Section 505 of the Act until the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: 1.) expiration of the exclusivity protection or 2.) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not deemed approved.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that if this application is ultimately approved, you will need to meet these requirements.

If you have any questions, contact Michelle Mathers, Regulatory Project Manager, at michelle.mathers@fda.hhs.gov or at (240) 402 2645.

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

ENCLOSURES:

Content of Labeling

Prescribing Information

Medication Guide

Instructions for Use

18 Page(s) of Draft Labeling have been Withheld in Full as B4 (CCI/TS) immediately following this page

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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/

WILLIAM H Dunn
05/06/2019 04:32:27 PM