NDA 208910/S-005

SUPPLEMENT APPROVAL

Azurity Pharmaceuticals, Inc.
Attention: Michael C. Beckloff
Chief Development Officer
7300 W 110th St, Ste 950
Overland Park, KS 66210

Dear Mr. Beckloff:

Please refer to your supplemental new drug application (sNDA) dated and received October 15, 2019, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FIRVANQ (vancomycin hydrochloride) for oral solution, 25 mg/mL and 50 mg/mL.

This "Changes Being Effected" sNDA provides for the following changes:

- Minor edit in the Product Title throughout the Prescribing Information and Carton and Container labeling,
- Section 2 DOSAGE AND ADMINISTRATION, Subsection 2.4 Preparation and Storage of Solutions of FIRVANQ, and
- Section 16 HOW SUPPLIED/STORAGE AND HANDLING

APPROVAL & LABELING

For the approval and labeling of this supplement, refer to the content of the labeling in SPL format and the updated carton and container labeling submitted on December 24, 2020, in response to the NDA 208910/S-006 approval letter (dated November 23, 2020).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Eva Zuffova, Regulatory Project Manager, at 301-796-0679.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy 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/

DMITRI IARIKOV
02/16/2022 07:55:44 AM