NDA 208910/S-004

SUPPLEMENT APPROVAL

RxM™ Therapeutics, LLC (A Wholly Owned Subsidiary of CutisPharma, Inc.)
c/o B&H Consulting Services, Inc.
Attention: Elizabeth N. Dupras, RAC
Senior Director, Regulatory Affairs
50 Division Street, Suite 206
Somerville, NJ 08876

Dear Ms. Dupras:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 18, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Firvanq (vancomycin hydrochloride) for Oral Solution, 25 mg/mL and 50 mg/mL.

This Prior Approval supplemental new drug application provides for update to the container labels of grape-flavored diluent, vancomycin hydrochloride powder component, and the carton for the FirvanqTM Oral Solution Kit.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 208910/S-004.**" Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Chinedu Ebonine, Regulatory Business Process Manager, at (240) 402 - 3448.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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