



NDA 214377/S-001

## **SUPPLEMENT APPROVAL**

Merck Sharp & Dohme LLC  
Attention: Najwa Mostafa  
Senior Director, Global Regulatory Affairs  
126 E. Lincoln Ave, PO Box 2000  
RY34B-322  
Rahway, NJ 07065-0900

Dear Ms. Mostafa:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 26, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VERQUVO (vericiguat) tablets, 2.5 mg and 5 mg.

This “Changes Being Effected” supplemental new drug application provides for addition of physician sample carton packaging.

### **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.

### **CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and 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 – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 214377/S-001.**” Approval of this submission by FDA is not required before the labeling is used.

### **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 Elizabeth Markovich, Regulatory Business Process Manager, at (301) 796 - 5071.

Sincerely,

*{See appended electronic signature page}*

*For:*

Gurpreet Gill-Sangha, PhD  
Branch Chief, Branch 3  
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



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
Date: 11/22/2022 02:44:41PM  
GUID: 502d0913000029f375128b0de8c50020