



NDA 016295/S-059

## SUPPLEMENT APPROVAL

CHEPLAPHARM Arzneimittel GmbH  
c/o Regulance LLC  
Attention: Bruce Thompson  
Principal and Consultant  
28 Hungerford Terrace  
Burlington, VT 05401

Dear Mr. Thompson:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 20, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DROXIA (hydroxyurea) capsules.

We also refer to our Safety Labeling Change (SLC) letter dated October 18, 2023, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for DROXIA (hydroxyurea) capsules. This information pertains to the risk of interference between hydroxyurea and certain currently marketed continuous glucose monitors (CGMs).

This Changes Being Effected supplemental new drug application provides for labeling update to add the following statement to the carton and container labels of Droxia (hydroxyurea) capsules of all strengths: "Dispense the accompanying Medication Guide to each patient."

### **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 016295/S-059.**" 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, contact Mikee Aguirre, Regulatory Business Process Manager, at [mikee.aguirre@fda.hhs.gov](mailto:mikee.aguirre@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, PhD  
Supervisor, Division of Product Quality Assessment IV  
Office of Product Quality Assessment II  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
Date: 6/20/2024 04:42:45PM  
GUID: 502d0913000029f375128b0de8c50020