



NDA 019865/S-22

## SUPPLEMENT APPROVAL

Covis Pharma GmbH  
Attention: Lavonne Patton, PhD  
Cardinal Health Regulatory Sciences  
7400 W 110<sup>th</sup> St., Ste. 300  
Overland Park, KS 66210

Dear Dr. Patton:

Please refer to your supplemental new drug application (sNDA) dated August 31, 2017, received August 31, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Betapace tablets.

We acknowledge receipt of your amendment dated February 26, 2019, which constituted a complete response to our February 28, 2018, action letter.

This Prior Approval supplemental new drug application provides for revisions to labeling consistent with the Pregnancy Lactation and Labeling Rule, (PLLR). Editorial and organizational revisions have also been made throughout out labeling. Substantive revisions have been made to the Dosage and Administration, Contraindications, Drug Interactions, Use in Specific Populations.

### **APPROVAL & LABELING**

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

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at [FDA.gov](http://www.fda.gov).<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

---

<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **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, please call Michael Monteleone, Associate Director for Labeling, at (301) 796-1952.

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, PharmD  
Deputy Director for Safety  
Division of Cardiology and Nephrology  
Office of Cardiology, Hematology, Endocrinology,  
and Nephrology  
Center for Drug Evaluation and Research

#### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

---

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

-----  
**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/  
-----

MARY R SOUTHWORTH  
06/03/2021 02:18:17 PM