



NDA 022165/S-006

## **SUPPLEMENT APPROVAL**

Assertio Therapeutics, Inc.  
Attention: Vasilios Iskos  
Senior Vice President, Operations  
100 S. Saunders Road  
Suite 300  
Lake Forest, IL 60045

Dear Vasilios Iskos:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 6, 2014, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cambia (diclofenac potassium) powder, for oral solution.

This “Changes Being Effected” supplemental new drug application provides for:

- Change in the “Direction of use” in the container and carton label.
- Other minor changes in the container and carton label including carton size/shape, text layout, color scheme change from green to purple/pink, product logo/drawing, Cambia™ to Cambia®, addition of web address of CambiaRx.com, and an image of a glass and a Cambia sachet on the carton label.

### **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.

### **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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and Medication Guide) 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.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at

<http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via 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(I)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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).

### **CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on February 28, 2024, 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 022165/S-006.**” 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, please contact Erica Keafer, Regulatory Business Process Manager, at (301) 796 – 1435 or [erica.keafer@fda.hhs.gov](mailto:erica.keafer@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Gurpreet Gill-Sangha, Ph.D.  
Supervisor  
Division of Product Quality Assessment II  
Office of Product Quality Assessment I  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Carton and Container Labeling



Gurpreet  
Gill Sangha

Digitally signed by Gurpreet Gill Sangha

Date: 4/23/2024 11:59:52AM

GUID: 5135f2ad000117842392c50c36c7f28a