

NDA 212520/S-001  
NDA 212520/S-002

## SUPPLEMENT APPROVAL

RVL Pharmaceuticals, Inc.  
a wholly-owned subsidiary of Osmotica Pharmaceutical Corp.  
Attention: Joann Stavole, MS, RAC  
Sr. Director, Regulatory Affairs  
400 Crossing Boulevard  
Bridgewater, NJ 08807

Dear Ms. Stavole:

Please refer to your supplemental new drug applications (sNDA) dated and received July 21 and 23, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for UPNEEQ (oxymetazoline hydrochloride ophthalmic solution), 0.1%. These Prior Approval supplemental new drug applications propose an alternate secondary packaging component, foil laminate, for UPNEEQ and an update to the labeling.

### **APPROVAL & LABELING**

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

We note that your July 23, 2020, submission includes final printed labeling (FPL) for your Prescribing Information and Instructions for Use. We have not reviewed this FPL. You are responsible for assuring that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

### **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.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Instructions for Use), 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 *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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

<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>.

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).

### **CARTON AND CONTAINER LABELING**

We acknowledge your July 23, 2020, submission containing final printed carton and container labeling.

### **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 Derek Alberding, Regulatory Health Project Manager, at (240) 402-0963.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, M.D.  
(Acting) Director  
Division of Ophthalmology  
Office of Specialty Medicine  
Center for Drug Evaluation and Research

### **ENCLOSURES:**

- Content of Labeling
  - Prescribing Information
  - Instructions for Use

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**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.**  
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/s/  
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WILEY A CHAMBERS  
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