

BLA 761094/S-012

BLA 761094/S-013

## SUPPLEMENT APPROVAL

Dompé farmaceutici S.p.A.  
Attention: Rensi Sutaria  
Senior Director, Global Regulatory Affairs  
One Marina Park Drive, Suite 1410  
Boston, MA 02210

Dear Rensi Sutaria:

Please refer to your supplemental biologics license applications (sBLAs), dated March 31, and April 21, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for OXERVATE (cenegermin-bkbj) ophthalmic solution. These Prior Approval sBLAs provide for the following changes:

BLA 761094/S-012: Additions to the ADVERSE REACTIONS section of the US Prescribing Information.

BLA 761094/S-013: Redesign of the “Delivery System Kit” to remove the (b) (4) box containing a weekly carton of OXERVATE multiple-dose vials.

### **APPROVAL & LABELING**

We have completed our review of these applications, as amended. They are 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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,<sup>1</sup> that is identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements.

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>

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<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 via publicly available labeling repositories.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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 “**Final Printed Carton and Container Labeling for approved BLA 761094/S-013.**” 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 BLA (in 21 CFR 600.80 and in 21 CFR 600.81). Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at [FDA.gov](http://FDA.gov).

If you have any questions about these supplements, call Derek Alberding, Clinical Analyst, at (240) 402-0963.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, MD  
Director  
Division of Ophthalmology  
Office of Specialty Medicine  
Office of New Drugs  
Center for Drug Evaluation and Research

### ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton and Container Labeling

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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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