



NDA 214028/S-003

**APPROVAL LETTER**

Abbvie Inc.  
Attention: Manisha Shah  
Associate Director, Regulatory Affairs  
5 Giralda Farms  
Madison, NJ 07940

Dear Ms. Shah:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 28, 2022, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vuity (pilocarpine hydrochloride 1.25% ophthalmic solution).

This Prior Approval supplemental new drug application provides for addition of a multidose 5 mL fill size.

**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.

We note that your December 19, 2022, submission includes final printed labeling (FPL) for your prescribing information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling 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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. 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.

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>.

**U.S. Food & Drug Administration**  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

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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**

We acknowledge your September 28, 2022, submission containing final printed carton and container labeling.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LCDR Maria Clary, Pharm.D., Regulatory Business Process Manager, at (240) 402 - 8615.

Sincerely,

*{See appended electronic signature page}*

David Lewis, Ph.D.  
Branch Chief, B2  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling  
Carton and Container Labeling



David  
Lewis

Digitally signed by David Lewis  
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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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MARIA A CLARY  
04/06/2023 11:45:31 AM