



NDA 021169/S-35  
NDA 021615/S-26

## SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.  
Attention: Kelly Rudnick, MSPH  
Associate Director, Global Regulatory Affairs  
1400 McKean Road,  
Spring House, PA 19477

Dear Ms. Rudnick:

Please refer to your supplemental New Drug Applications (sNDAs) dated and received February 3, 2021, and your amendments, submitted under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Razadyne (galantamine) tablets and Razadyne ER (galantamine) extended-release capsules.

These Prior Approval sNDAs provide for the addition of information regarding extrapyramidal reactions to Warnings and Precautions, and Adverse Reactions sections of the Prescribing Information.

### **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.

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 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(I)(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, contact Justine Kankam, Regulatory Project Manager, at (301)-837-7650 or via email [NanaYaa.Kankam@fda.hhs.gov](mailto:NanaYaa.Kankam@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Eric Bastings, MD  
Director (Acting)  
Division of Neurology 1  
Office of Neuroscience  
Center for Drug Evaluation and Research

#### ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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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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