



NDA 017862/S-064

## SUPPLEMENT APPROVAL

Hikma Pharmaceuticals USA, Inc.  
Attention: Nicole Weyermann  
Senior Associate  
2 Esterbrook Lane  
Cherry Hill, NJ 08003

Dear Nicole Weyermann:

Please refer to your supplemental new drug application (sNDA) dated and received October 31, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reglan (metoclopramide) injection.

This Prior Approval sNDA provides for revisions to several sections of the Prescribing Information, including the BOXED WARNING, WARNINGS, and DOSAGE AND ADMINISTRATION to clarify the risks of tardive dyskinesia relative to the benefits of treatment for relief of symptoms of acute and recurrent diabetic gastroparesis in adults. Other updates were made to recommended dosage adjustments for patients with hepatic impairment, renal impairment, CYP2D6 poor metabolizer status, and those receiving concomitant strong CYP2D6 inhibitors in the PRECAUTIONS, *Drug Interactions* and DOSAGE AND ADMINISTRATION sections.

### **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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- Added the approval date in the Medication Guide.

### **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 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.

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

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>

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).

## **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 Maureen Dewey, Senior Regulatory Project Manager, at [Maureen.Dewey@fda.hhs.gov](mailto:Maureen.Dewey@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D., M.P.H.  
Deputy Director for Safety  
Division of Gastroenterology (DG)  
Office of Immunology and Inflammation (OI)  
Center for Drug Evaluation and Research

## ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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<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>.

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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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