NDA 203441/S-28

SUPPLEMENT APPROVAL

Takeda Pharmaceuticals U.S.A., Inc.
Attention: Ankith Devunapalli
Director, Gloval Regulatory Affairs, MS, MBA
500 Kendall Street
Cambridge, MA 02142

Dear Ankith Devunapalli:

Please refer to your supplemental new drug application (sNDA) dated August 26, 2026, , submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gattex (teduglutide) for injection.

This Prior Approval supplemental new drug application provides for modifications to the approved Gattex (teduglutide) risk evaluation and mitigation strategy (REMS). This supplement is in response to our August 20, 2026, REMS Modification Notification letter.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Gattex was originally approved on December 21, 2012 and the most recent REMS modification was approved on August 13, 2025. The REMS consists of elements to assure safe use (ETASU) and a timetable for submission of assessments of the REMS.

Because we determined that a REMS is no longer necessary to ensure the benefits of Gattex outweigh its risks you were required to submit a REMS modification to eliminate the REMS as outlined in our REMS Modification Notification letter dated August 20, 2026.

Elements to Assure Safe Use: We have determined that the elements to assure safe use are no longer necessary because a REMS is no longer necessary to ensure the benefits of the drug outweigh the risks of possible neoplastic growth and enhancement of gastric, small intestinal (duodenum, ileum, and jejunum), and colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disordersassociated with the use of Gattex based on the following data:

- Data from the **integrated study report (ISR)** from TED-R13-002 for Gattex demonstrated stable rates of adverse events that are consistent with the US Prescribing Information (USPI) and that US patients taking Gattex received colonoscopies at rates 2.5 – 3 times more than those not on Gattex.
- Data from recent **Gattex REMS Assessments** (2017-2024), with a focus on the 12-year REMS Assessment demonstrated a consistent, small patient and prescriber population with small increases in usage from year to year.
- An evaluation of Gattex **drug utilization data** determined that approximately 80% of prescriptions written for Gattex from 2020-2024 were written by prescribers who are specialists and expected to be familiar with the risks and monitoring.
- **Interviews** conducted with gastroenterologist specialists from the CDER Network of Experts revealed prescribers of Gattex in both adult and pediatric patients were well-informed of the serious risks associated with Gattex and recommended monitoring, including awareness of postmarket reports of gastric small intestinal polyps and screening for them prior to the inclusion into USPI.
- Currently published best practice **clinical resources** for the treatment of SBS include Gattex as a therapy for use in specific patients who have maximized other pharmacologic treatments. Both benefits and risks are adequately outlined, and these references are expected to remain readily available to prescribers after the REMS is released.

Therefore, because the elements to assure safe use are no longer necessary to ensure the benefits outweigh the risks, a REMS is no longer required for Gattex.

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 Jacqueline LeeHoffman, Safety Regulatory Project Manager, at Jacqueline.LeeHoffman@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 (OII)
Center for Drug Evaluation and Research

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/s/

JOYCE A KORVICK
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