



BLA 125360/S-107

SUPPLEMENT APPROVAL

Merz Pharmaceuticals GmbH
c/o Merz Pharmaceuticals LLC
Attention: Jordan Holmes, Ph.D.
Regulatory Affairs Manager
6601 Six Forks Road
Suite 400
Raleigh, NC 27615

Dear Jordan Holmes:

Please refer to your supplemental biologics license application (sBLA) dated and received October 20, 2025, submitted under section 351(a) of the Public Health Service Act for Xeomin (IncobotulinumtoxinA) Injection.

This Prior Approval supplemental biologics license application provides for draft artwork for new secondary packaging for all dosing presentations and samples, including: Merz Therapeutics Vial Labels, Merz Therapeutics Cartons.

APPROVAL & LABELING

We have completed our review of this sBLA. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

We acknowledge your February 20, 2026, submission containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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).

If you have any questions, call Melinda Bauerlien, Senior Regulatory Business Process Manager, at (301) 796 - 0906.

Sincerely,

{See appended electronic signature page}

Ashutosh Rao, Ph.D. for
Susan Rosencrance, Ph.D.
Deputy Office Director
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Carton and Container Labeling



Ashutosh
Rao

Digitally signed by Ashutosh Rao

Date: 3/20/2026 08:41:00AM

GUID: 508da6d9000264c90e95985d32430b09