BLA 208157/S-008

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Mehul Patel
Manager, Regulatory Affairs
One Baxter Parkway
Deerfield, IL 60015

Dear Mehul Patel:

Please refer to your supplemental biologics license application (sBLA), dated and received October 11, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Myxredlin (insulin human) in sodium chloride injection.

We also refer to our email dated November 12, 2024, informing you that we began evaluating a Newly Identified Safety Signal (NISS) on August 7, 2024, for your product, Myxredlin, regarding medication errors due to confusion between similarly labeled Baxter products.

This Prior Approval sBLA provides for modifications to the carton and container labeling to further differentiate Myxredlin from similarly labeled Baxter products to help mitigate the potential risk of medication errors.

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.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on December 13, 2024, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 208157/S-008**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 supplement 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, contact Marisa Petruccelli, Safety Regulatory Project Manager, at marisa.petruccelli@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Monika Houstoun, Pharm.D., M.P.H.
Deputy Director for Safety
Division of Diabetes, Lipid Disorders, and Obesity
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Prescribing Information (version previously approved on June 4, 2020)
- Carton and Container Labeling

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.

/s/

MONIKA A HOUSTOUN
03/07/2025 09:15:34 AM