



BLA 761108/S-015

SUPPLEMENT APPROVAL

Alexion Pharmaceuticals, Inc.
Attention: Mary F. Lyons, RAC
Director, Global Regulatory Affairs
Global Labeling and US Life Cycle Management
121 Seaport Boulevard, Boston, MA 02210

Dear Ms. Lyons:

Please refer to your supplemental biologics license application (sBLA), received on March 29, 2021, submitted under section 351(a) of the Public Health Service Act for Ultomiris (ravulizumab-cwvz) injection.

This "Changes Being Effected" supplemental biologics application provides a revision on the top panel of the 3 mL carton (NDC 25682-025-01). The top panel of the 3 mL carton states "30 mL Single-dose vial" where it should correctly state "3 mL Single-dose vial".

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELING

We acknowledge your March 29, 2021, 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 (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 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 Caden Brennen, Regulatory Project Manager, at 301-796-6591 or at Caden.Brennen@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ann Farrell, MD
Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE:

- 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/

ANN T FARRELL
04/22/2021 09:49:06 AM