

BLA 761055/S-076

SUPPLEMENT APPROVAL

Regeneron Pharmaceuticals, Inc
Attention: James H. Schlick, MBA, RPh
Director, Regulatory Affairs CMC and Combination Products
777 Old Saw Mill River Road
Tarrytown, NY 10579

Dear Dr. Schlick:

Please refer to your supplemental biologics license application (sBLA) dated and received on October 15, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Dupixent (dupilumab) injection.

This Changes Being Effected sBLA provides for the addition of the statement “Per Pre-filled Syringe,” or “Per Pre-filled Pen,” to the dose bar of the pre-filled syringe and pre-filled pen cartons, respectively, in response to Agency labeling comments dated June 6, 2025.

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 enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to 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 “**Product Correspondence – Final Printed Carton and Container Labeling for approved BLA 761055/S-076.**” 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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, contact Asma U. Husna-Islam, PharmD, Regulatory Project Manager, at asma.husna-islam@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S): 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/

TATIANA OUSSOVA
07/15/2026 03:19:32 PM