



Our STN: BL 125566/866

SUPPLEMENT APPROVAL

August 9, 2023

Takeda Pharmaceuticals U.S.A., Inc.
Attention: Mercyanne A. Publico MS, PMP
95 Hayden Avenue
Lexington, MA 02142

Dear Ms. Publico:

We have approved your request received February 7, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for ADYNOVATE to revise the US Prescribing Information (USPI) warning statement related to anaphylaxis, addition of anaphylactic reaction as a post marketing ADR and to update the ADR preferred term “drug eruption” to “rash pruritic”.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling Package Insert, Patient Package, and Instructions for Use submitted under amendment 8 dated August 8, 2023, for ADYNOVATE baxjet-iii and under amendment 9 dated August 9, 2023, for ADYNOVATE baxjet-ii.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the Package Insert, Patient Package Insert, and Instructions for Use submitted on August 8, 2023, for ADYNOVATE baxjet-iii and under amendment 9 dated August 9, 2023, for ADYNOVATE baxjet-ii.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125566/866 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Nicole Verdun, MD
Acting Director
Division of Clinical Evaluation Hematology
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research