



BLA 125516/S-041

## SUPPLEMENT APPROVAL

United Therapeutics Corporation  
Attention: Nicole Wilkerson  
Director, Regulatory Affairs  
55 T.W. Alexander Drive  
PO Box 14186  
Research Triangle Park, NC 27709

Dear Nicole Wilkerson:

Please refer to your supplemental biologics license application (sBLA) received May 30, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Unituxin (dinutuximab) Injection, for intravenous use.

This Prior Approval supplemental biologics application provides for the following updates to Unituxin prescribing information:

- Addition of aHUS to Section 2.3 Dosage Modifications under Table 3 (Adverse Reactions Requiring Permanent Discontinuation of Unituxin), after an inadvertent omission, to correspond to approved instructions provided in Section 5.8 Warnings and Precautions – Atypical Hemolytic Uremic Syndrome.

### **APPROVAL**

We have completed our review of this sBLA, as amended. This supplement is approved as amended.

### **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.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at

FDA.gov,<sup>1</sup> that is identical to the enclosed labeling (text for the Prescribing Information), and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

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*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effectuated” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **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).

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

If you have any questions, contact Tselaine Jones Smith, Regulatory Project Manager, at [Tselaine.JonesSmith@fda.hhs.gov](mailto:Tselaine.JonesSmith@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Nicole Drezner, MD  
Deputy Division Director  
Division of Oncology 2  
Office of Oncologic Diseases  
Office of New Drugs  
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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**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.**  
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/s/  
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NICOLE L DREZNER  
10/10/2025 07:11:57 PM