



BLA 761148/S-011

## **SUPPLEMENT APPROVAL**

Spectrum Pharmaceuticals, Inc.  
Attention: Vasilios Iskos  
Senior Vice President, Operations  
100 S. Saunders Road  
Suite 300  
Lake Forest, IL 60045

Dear Vasilios Iskos:

Please refer to your supplemental biologics license application (sBLA) dated and received June 18, 2025, submitted under section 351(a) of the Public Health Service Act for Rolvedon (eflapegrestim-xnst) injection.

This “Changes Being Effectuated in 30 days” sBLA provides for an extension of the allowable Time Out of Refrigeration (TOR) for Rolvedon from the currently approved 12 hours to 72 hours.

### **APPROVAL & LABELING**

We have completed our review of this sBLA. 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](https://www.fda.gov/fda/gov)<sup>1</sup>, that is identical to the enclosed labeling (text for the prescribing information, text for the patient package insert, and instructions for use) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements. If the content of labeling in SPL format initially submitted with this CBE-30 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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

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 MS Word format that includes the changes approved in this supplemental application.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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, call Melinda Bauerlien, Senior Regulatory Business Process Manager, at (301) 796 - 0906.

Sincerely,

*{See appended electronic signature page}*

Susan Kirshner, Ph.D.  
Director  
Division of Product Quality Assessment XV  
Office of Product Quality Assessment III  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling



Susan  
Kirshner

Digitally signed by Susan Kirshner

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