



BLA 125294/S-048

## **SUPPLEMENT APPROVAL**

Sicor Biotech UAB  
c/o Teva Branded Pharmaceutical Products R&D, Inc.  
Attention: Arthur Merlin d'Estreux, M.Sc, MTOPRA  
Associate Director, Regulatory Affairs  
41 Moores Road, P.O. Box 4011  
Frazer, PA 19355

Dear Mr. Arthur Merlin d'Estreux:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received April 11, 2019, and your amendment, submitted under section 351(a) of the Public Health Service Act for Granix (tbo-filgrastim) injection, 300 mcg/0.5 mL and 480 mcg/0.8 mL prefilled syringe.

This Prior Approval supplemental biologics license application provides for an update to the Granix Syringe outer cartons to appear with the same design features as the vial cartons which were approved under S-045 on July 31, 2018. The changes incorporated on each carton include new corporate branding elements, strengths highlighted within a rondel, and syringe information placed in close proximity to strength information.

### **APPROVAL & LABELING**

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

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling and carton and container labeling submitted on September 24, 2019, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the 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 125294/ S-048.**” 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, 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 Kelly Ballard, Regulatory Business Process Manager, at (301) 348 - 3054.

Sincerely,

*{See appended electronic signature page}*

Kathleen A. Clouse, Ph.D.  
Director  
Division of Biotechnology Review and Research I  
Office of Biotechnology Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling