



NDA 020622/S-109

## SUPPLEMENT APPROVAL

Teva Pharmaceuticals USA  
Attention: Angela Randall  
Director, Regulatory Affairs Labeling  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Ms. Volovsky:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 20, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Copaxone (glatiramer acetate) Injection, 20 mg/mL and 40 mg/mL Pre-Filled Syringe.

This Prior Approval supplemental new drug application provides for packaging information and design changes to the drug product syringe labels, blister labeling, and carton labeling.

### **APPROVAL & LABELING**

We have completed our review of this supplemental application. 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 immediate container labels that are identical to enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020622/S-109.**” Approval of this submission by FDA is not required before the labeling is used.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

*{See appended electronic signature page}*

David Lewis, Pharm.D.  
Branch Chief, Branch II  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



David  
Lewis

Digitally signed by David Lewis

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