



NDA 016750/S-032

## **SUPPLEMENT APPROVAL**

Amphastar Pharmaceuticals, Inc.  
Attention: Gisela Sharp  
Associate Director, Regulatory Affairs  
11570 6th Street  
Rancho Cucamonga, CA 91730

Dear Ms. Sharp:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 2, 2021, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cortrosyn® (Cosyntropin) for Injection.

This “Changes Being Effected” supplemental new drug application provides for labeling updates based on the supplement request letter sent by the Agency dated June 4, 2021 to revise the PI and carton/container labels.

### **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.

### **CONTENT OF LABELING**

We note that your July 2, 2021, submission includes final printed labeling (FPL) for your prescribing information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

We acknowledge your June 4, 2021, submission containing final printed labeling (FPL) for your prescribing information.

### **CARTON AND CONTAINER LABELS**

We acknowledge your December 13, 2021, submission containing final printed carton and container labeling.

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Christopher LaFleur, Regulatory Business Process Manager at Christopher.LaFleur@FDA.HHS.gov or (240) 402-4724.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.  
Chief, Branch 1  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling  
Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
Date: 12/14/2021 05:21:19PM  
GUID: 502d0913000029f375128b0de8c50020