



NDA 202832/S-006

## **SUPPLEMENT APPROVAL**

Medefil Inc  
Attention: Pradeep Aggarwal  
President and CEO  
405 Windy Point Drive  
Glendale Heights, IL 60139

Dear Mr. Aggarwal:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 28, 2022, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sodium Chloride Injection USP, 0.9%.

This “Changes Being Effected” supplemental new drug application provides for change in syringe label and dispenser box label color.

### **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.

### **CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and 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 – 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 Labels for approved NDA 202832/S-006.**” 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 Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure(s):  
Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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