



NDA 211844/S-001

## **SUPPLEMENT APPROVAL**

Inforlife SA  
c/o Interchem Corp  
Attention: Jeanne Squeglia  
120 Route 17 North  
Paramus, NJ 07652

Dear Ms. Squeglia:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 19, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Midazolam in sodium chloride injection, 1 mg/mL.

This “Changes Being Effected” supplemental new drug application provides for for minor formatting revisions in Bag, overwrap and carton 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.

### **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 211844/S-001.**” 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).

NDA 211844/S-001

Page 2

If you have any questions, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

*{See appended electronic signature page}*

Gurpreet Gill-Sangha, Ph.D.,  
Branch Chief  
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



Hasmukh  
Patel

Digitally signed by Hasmukh Patel

Date: 10/19/2021 04:42:03PM

GUID: 508da71e00029e3864a0ad90c32d1866

Comments: Signed for Dr. Gurpreet Gill-Sangha.