



NDA 022276/S-018

**SUPPLEMENT APPROVAL**

Exela Pharma Sciences, LLC.  
Attention: Aruna Koganti  
Vice President, Clinical and Regulatory Affairs  
P.O. Box 818  
1245 Blowing Rock Blvd.  
Lenoir, NC 28645

Dear Aruna Koganti:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 3, 2020, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicardipine Hydrochloride Injection, 0.1 mg/mL & 0.2 mg/mL.

This “Changes Being Effected” supplemental new drug application provides for Labeling change to Nicardipine Hydrochloride in 0.9% Sodium Chloride Injection, as follows: – Removal of the statement “Double Concentration: Check Infusion Rate” from the bag (printing plate) of Nicardipine Hydrochloride in 0.9% Sodium Chloride Injection 0.2 mg/mL, according to the Reference Listed Drug (RLD) Cardene I.V 0.1 mg/mL and 0.2 mg/mL, NDA 19-734.

**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 and carton and container labels submitted on December 3, 2020, 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 022276/S-018.**” 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 Elizabeth Eydelman, MPH, Regulatory Business Process Manager, at (301) 796 - 5071.

Sincerely,

*{See appended electronic signature page}*

Gurpreet Gill-Sangha, PhD  
Branch Chief, Branch 3  
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



Gurpreet  
Gill Sangha

Digitally signed by Gurpreet Gill Sangha  
Date: 6/01/2021 11:33:36AM  
GUID: 5135f2ad000117842392c50c36c7f28a