NDA 206628/S-017

APPROVAL LETTER

HQ Specialty Pharma Corporation
Attention: Jeanne Squeglia
VP Technical
120 Route 17 North
Paramus, NJ 07652

Dear Ms. Squeglia:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 8, 2021, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dexmedetomidine Hydrochloride Injection.

This Prior Approval supplemental new drug application provides for a change in the size of a container from 100 mL bag to 50 mL bag for 200µg/50 mL bag presentation of Dexmedetomidine Hydrochloride Injection.

APPROVAL

We have completed our review of this supplemental application, as amended. This supplement is approved.

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, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, PhD
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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