21-038

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION 21-038

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Approval Package for:

Application Number 21-038

Trade Name Precedex

Generic Name dexmedetomidine

Sponsor Abbott Labs.

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-038

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

NDA 21-038

Food and Drug Administration
Rockville MD 20857

Abbott Laboratories
Hospital Products Division
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

Attention: Thomas F. Willer, Ph.D.
Assistant Director, Regulatory Affairs

DEC 17 1999

Dear Dr. Willer:

Please refer to your new drug application (NDA) dated December 18, 1998, received December 18, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PRECEDEX (dexmedetomidine hydrochloride injection) 2 mL ampule/2 mL vial, 100 mcg/mL.

We acknowledge receipt of your submissions dated February 4, March 10, 15, 30 and 31, April 30, May 4, 10, 12, 21, and 24, June 17 and 18, July 2, August 12, 17, 20, and 27, September 2, 3, 10, 16, and 20, October 1, 5, 8, 19, and 27, November 1, 4, 17, and 19, December 2, 3, 5, 6, 7, 9, 14, 16, and 17, 1999.

This new drug application provides for the use of dexmedetomidine hydrochloride 2 mL ampule/2 mL vial, 100 mcg/mL, for sedation of initially intubated and mechanically ventilated patients in an intensive care unit (ICU) setting.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and to the carton and container labels submitted on December 17, 1999. Marketing the product with FPL that is not identical to the approved labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-038." Approval of this submission by FDA is not required before the labeling is used.

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