NDA 206143/S-008
NDA 209964/S-002

GENERAL ADVICE

Amgen Inc.
Attention: Christine Kubik
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop 27-2-D
Thousand Oaks, CA 91320-1799

Dear Ms. Kubik:

Please refer to your supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Corlanor (ivabradine) 5 mg and 7.5 mg Tablets (NDA 206143) and Corlanor (ivabradine) 1 mg/mL Oral Solution (NDA 209964).

We also refer to our approval letter dated August 4, 2021, which contained an error.

The August 4, 2021 Approval letter was missing an image of the 1 mg/mL oral solution label.

This General Advice letter acknowledges the error described above and incorporates the correction of the error. The effective approval date will remain August 4, 2021, the date of the original letter.

If you have any questions, call Lori Anne Wachter, RN, BSN, RAC, Regulatory Project Manager for Safety, at 301 796-3975.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology and Nephrology
Center for Drug Evaluation and Research

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/s/

MARY R SOUTHWORTH
08/10/2021 12:28:43 PM