DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125522/S-011

SUPPLEMENT APPROVAL

Amgen, Inc.
Attention: Adam Rupert
Senior Manager, Regulatory Affairs
One Amgen Center Drive, Mail Stop 17-2-B
Thousand Oaks, CA 91320-1799

Dear Mr. Rupert:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received December 9, 2016, submitted under section 351(a) of the Public Health Service Act for Repatha (evolocumab) injection.

This Prior Approval supplemental biologics application provides for a revision to the Repatha Pushtronex™ On-Body Infusor device labeling to increase the prominence (by bolding) of the text "on-body infusor" in response to our November 3, 2016 supplement request letter.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Kati Johnson, Senior Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

James P. Smith, MD, MS
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE: Repatha Pushtronex™ device labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JAMES P SMITH
01/03/2017