DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021332/S-026

SUPPLEMENT APPROVAL

AstraZeneca AB
Attention: Mary Whealy
Global Reg Affairs Director, Cardiovascular
One MedImmune Way
Gaithersburg, MD 20878

Dear Ms. Whealy:

Please refer to your supplemental New Drug Application (sNDA) dated and received February 24, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Symlin (pramlintide acetate) injection.

This supplemental new drug application provides for proposed modifications to the approved risk evaluation and mitigation strategy (REMS). This supplement is in response to our February 13, 2017, REMS Modification Notification letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Symlin (pramlintide acetate) injection was originally approved on June 27, 2014, and the most recent REMS modification was approved on August 7, 2015. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS. In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the following REMS modifications: elimination of the communication plan and release from the requirement for the REMS.

Because the communication plan has been completed and the assessment demonstrates that the communication plan has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Symlin (pramlintide acetate) injection.

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 Richard Whitehead, M.S., Regulatory Project Manager, at (301) 796-4945.

Sincerely,

{See appended electronic signature page}

Jennifer Rodriguez Pippins, M.D., M.P.H.
Deputy Director for Safety
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

JENNIFER R PIPPINS
03/08/2017