DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022200/S-010

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

AstraZeneca AB
Attention: Emery Gigger
Regulatory Affairs Director
1800 Concord Pike
P.O. Box 8355
Wilmington DE 19803-8355

Dear Mr. Gigger:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 27, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bydureon (exenatide extended-release for injectable suspension).

We acknowledge receipt of your amendment dated March 7, 2014 and your risk evaluation and mitigation strategy (REMS) assessment dated January 27, 2014. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

This supplemental new drug application proposes to eliminate the requirement for the approved Bydureon REMS.

APPROVAL

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Bydureon was originally approved on January 27, 2012. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Bydureon.

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 Bydureon (exenatide extended-release).

If you have any questions, please call Martin White, M.S., Regulatory Project Manager, at (240) 402-6018.

Sincerely,

{See appended electronic signature page}

Jennifer Rodriguez Pippins, M.D., MPH
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
04/29/2015