DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021773/S-031

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Amylin Pharmaceuticals Inc.
Attention: Orville Kolterman, M.D.
Sr. Vice President, Chief Medical Officer
9360 Towne Centre Drive, Suite 110
San Diego, CA 92121

Dear Dr. Kolterman:

Please refer to your Supplemental New Drug Application (sNDA) dated July 6, 2011, received July 7, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Byetta (exenatide) Injection.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 29, 2011 and amended on June 6, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Byetta (exenatide) REMS.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Byetta (exenatide) was originally approved on October 30, 2009. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Byetta (exenatide).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. In addition, the REMS assessment demonstrates that the communication plan has been completed and has met its goals. Therefore, we have determined that it is no longer necessary to include the Medication Guide and the communication plan as elements of the approved REMS to ensure that the benefits of the drug outweigh the risks, and the REMS for Byetta (exenatide) is no longer required.

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We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 Pooja Dharia, Pharm.D., Regulatory Project Manager, at (301) 796-5332.

Sincerely,

{See appended electronic signature page}

Amy G. Egan, 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/

AMY G EGAN
08/05/2011