DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021332/S-020

SUPPLEMENT APPROVAL

Amylin Pharmaceuticals, Inc.
Attention: Orville Kolterman, M.D.
Sr. Vice President, Research & Development
9360 Towne Centre Drive, Suite 110
San Diego, CA 92121-3030

Dear Dr. Kolterman:

Please refer to your Supplemental New Drug Application (sNDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SYMLIN (pramlintide acetate) Injection.

We acknowledge receipt of your amendment dated March 4, 2011.

This "Prior Approval" supplemental new drug application updates the cartons for SymlinPen 60 and SymlinPen 120 to indicate that the active ingredient is made in Belgium.

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

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your March 4, 2011, submission containing final printed carton and container labels.

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 Rachel Hartford, Regulatory Project Manager, at (301) 796-0331.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
SymlinPen 60 trade and sample carton labels
SymlinPen 120 trade and sample carton labels

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/s/

MARY H PARKS
01/03/2012