DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-332/S-010

Amylin Pharmaceuticals, Inc
Attention: Dawn Viveash, M.D.
Vice President, Regulatory Affairs and Safety
9360 Towne Centre Drive, Suite 110
San Diego, CA 92121-3030

SUPPLEMENT APPROVAL

Dear Dr. Viveash:

Please refer to your supplemental new drug application dated December 20, 2007, received December 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Symlin, (pramlintide acetate) injection.

We acknowledge receipt of your submission dated July 17, 2008.

This "Changes Being Effected" supplemental new drug application provides for the addition of a "Post Marketing Experience" subsection with information on injection site reactions to the **ADVERSE REACTIONS** section of the Package Insert.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for package insert submitted on July 17, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-332/S-010."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

Enclosure: Package Insert

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

/s/

Mary Parks

8/4/2008 09:17:06 AM