DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-773/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

Dear Dr. Viveash:

Please refer to your supplemental new drug application dated June 8, 2007, received June 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Byetta (exenatide) Injection.

We acknowledge receipt of your submissions dated January 18, and May 27, 2008.

This supplemental new drug application provides for revisions to the 5 mcg and 10 mcg Pen User Manuals.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (Pen User Manuals, submitted May 27, 2008).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-773/S-010**." Approval of this submission by FDA is not required before the labeling is used.

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 John Bishai, Regulatory Project Manager, at (301) 796-1311.

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: 5 mcg and 10 mcg Pen User Manuals

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

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