DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-773/S-004

Amylin Pharmaceuticals, Inc.
Attention: John F. Wood, MBA, RAC
Executive Director, Regulatory Affairs
9360 Towne Centre Drive, Suite 110
San Diego, CA 92121-3030

Dear Mr. Wood:

Please refer to your supplemental new drug application dated April 11, 2006, received April 12, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Byetta (exenatide) Injection.

We acknowledge receipt of your submission dated October 11, 2006.

This "Changes Being Effected" supplemental new drug application provides for changes to the package insert (PI) and patient product information (PPI). Proposed changes to the PI include additional information in the **PRECAUTIONS** Section, **Information for Patients** subsection, and the **ADVERSE REACTIONS** Section, **Spontaneous Data** subsection based on events reported postmarketing. Proposed changes to the PPI include additional information in the **How should I use BYETTA?** section.

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 (package insert submitted on October 11, 2006 and patient product information submitted on April 11, 2006).

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 submissions "**FPL for approved supplement NDA 21-773/S-004**." 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Lina AlJuburi, Pharm.D., M.S., Regulatory Project Manager, at 301-796-1168.

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: Package Insert and Patient Product Information

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

10/12/2006 08:09:33 PM