DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-773/S-012

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

Dear Dr. Viveash:

Please refer to your supplemental new drug application dated October 26, 2007, received October 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Byetta (exenatide) injection.

We acknowledge receipt of your submission dated December 21, 2007.

This "Changes Being Effected" supplemental new drug application provides for updates to the package insert (PI) and patient package insert (PPI) to include language regarding acute pancreatitis.

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.

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 Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

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 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

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