



NDA 21-773/S-005

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

Dear Mr. Wood:

Please refer to your supplemental new drug application dated April 28, 2006, received May 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Byetta (exenatide) Injection, 5 mcg and 10 mcg.

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

We have completed our review of this application. 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 (5 mcg and 10 mcg Pen User Manuals, both submitted on April 28, 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 submission "**FPL for approved supplement NDA 21-773/S-005.**" 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).

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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: Byetta 5 mcg Pen User Manual
Byetta 10 mcg Pen User Manual

**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
11/1/2006 10:00:24 PM