



NDA 21-773/S-007

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 6, 2006, received October 10, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Byetta (exenatide) Injection, 5 mcg and 10 mcg.

We acknowledge receipt of your submissions dated January 30 and February 7, 2007.

This supplemental new drug application provides for in-use storage condition up to 25°C for 30 days during the 24-month expiration dating period.

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 (text for package insert, text for patient product information, pen labels for 5 mcg and 10 mcg, carton labels for 5 mcg and 10 mcg all submitted on February 7, 2007, and pen user manuals for 5 mcg and 10 mcg submitted on January 30, 2007).

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-007.**" Approval of this submission by FDA is not required before the labeling is used.

Within 21 days of the date of this letter, please submit 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 in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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, 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

Enclosure: Package Insert, Patient Product Information, Pen Labels for 5 mcg and 10 mcg, Container Labels for 5 mcg and 10 mcg, Pen User Manuals for 5 mcg and 10 mcg

**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
2/10/2007 06:48:30 AM