DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-332/S-006

SUPPLEMENT APPROVAL

Amylin Pharmaceuticals, Inc.
Attention: Dawn Viveash, MD
Vice President, Regulatory Affairs and Safety
9360 Town Centre Drive, Suite 110
San Diego, CA 92121-3030

Dear Dr. Viveash:

Please refer to your supplemental new drug application dated June 27, 2006, received June 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Symlin (pramlintide acetate) Injection.

We acknowledge receipt of your submissions dated December 7 and 11, 2006, and January 31, March 12, April 4, May 14 and 24, and September 19 and 25(secure email), 2007.

Your submission of May 24, 2007, constituted a complete response to our December 22, 2006, action letter.

This supplemental new drug application provides for the following changes for Symlin (pramlintide acetate) Injection:

1. A new strength of Symlin, 1000 mcg/mL;
2. Two disposable pen-injectors containing 1000 mcg/mL Symlin:
   - **SymlinPen 60** delivers 15 mcg, 30 mcg, 45 mcg, or 60 mcg per dose and
   - **SymlinPen 120** delivers 60 mcg or 120 mcg per dose;
3. Revised Package Insert (PI) and Medication Guide (MG);
4. Addition of three separate Patient Instructions for Use (PIU)
   - for Vials,
   - for SymlinPen 60,
   - for SymlinPen 120;
5. For the immediate container and carton label for the **Vial**, the strength is now stated as "**600 mcg/mL**" instead of "0.6 mg/mL" and the in-use storage time is extended to 30 days from 28.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling (submitted by email September 25, 2007; text for the package insert, Medication Guide, text for the Patient Instructions for Use - Vial, text for the Patient Instructions for Use - SymlinPen 60, and text for the Patient Instructions for Use - SymlinPen 120). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-332/S-006**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels for 5 mL Vials submitted June 27, 2006; carton and immediate container labels for SymlinPen 60 submitted May 24, 2007; and carton and immediate container labels for SymlinPen 120 submitted September 19, 2007; as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-332/S-006**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

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 Enid Galliers, Chief, Project Management Staff, at 301-796-1211.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products (DMEP)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
Package Insert
Medication Guide
Patient Instructions for Use (5 mL Vial, 600 mcg/mL)
Patient Instructions for Use (1.5 mL **SymlinPen 60**, 1000 mcg/mL [15-30-45-60 mcg])
Patient Instructions for Use (2.7 mL **SymlinPen 120**, 1000 mcg/mL [60-120 mcg])
Vial container & carton labels
SymlinPen 60 container & carton labels
SymlinPen 120 container & carton labels

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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