



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-773/S-002

NDA 21-773/S-006

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 applications dated February 27, 2006, received February 28, 2006, and September 15, 2006, received September 18, 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 April 14, June 27, August 3, and December 21, 2006, to supplement 002 and November 13 and December 21, 2006, to supplement 006.

These supplemental new drug applications provide for: (S-002) the use of exenatide in patients with type 2 diabetes mellitus who are using a thiazolidinedione alone or in combination with metformin but have not achieved adequate glycemic control and (S-006) additional language to the **PRECAUTIONS, Drug Interactions** and **ADVERSE REACTIONS, Spontaneous Data** sections of the package insert regarding concomitant warfarin use and increased International Normalized Ratio (INR).

We have completed our review of these applications, as amended. These applications are 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 the package insert and text for the patient product information submitted on December 21, 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-002 and S-006.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly 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

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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Mary Parks  
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