



NDA 021773/S-026

**SUPPLEMENT APPROVAL**

Amylin Pharmaceuticals, Inc.  
Attention: Orville G. Kolterman, M.D.  
Sr. Vice President, Chief Medical Officer  
9360 Towne Centre Drive  
San Diego, CA 92121-3030

Dear Dr. Kolterman:

Please refer to your Supplemental New Drug Application (sNDA) dated June 16, 2010, received June 17, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Byetta (exenatide) injection.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Byetta 5 mcg and 10 mcg carton labels.

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

**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 <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product to this division.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

### **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 Pooja Dharia, Pharm.D., Regulatory Project Manager, at (301) 796-5332.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE:

Carton Labels (5 mcg and 10 mcg)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21773	SUPPL-26	AMYLIN PHARMACEUTICA LS INC	BYETTA (EXENATIDE) INJ,SOL 0.25MG/ML

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/s/

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MARY H PARKS  
08/13/2010