



NDA 201281/S-002

**SUPPLEMENT APPROVAL**

Boehringer Ingelheim Pharmaceuticals, Inc.  
Attention: Dawn Collette  
Associate Director, CMC Regulatory Affairs  
900 Ridgebury Road/ P.O. Box 368  
Ridgefield, CT 06877-0368

Dear Ms. Collette:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 27, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Jentaduetto (linagliptin and metformin hydrochloride) tablets, 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg.

We acknowledge receipt of your amendment dated June 13, 2012.

This "Prior Approval" supplemental new drug application proposes to add a picture of the tablet to the carton and container labels to provide better differentiation.

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

**CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on June 13, 2012, 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 (June 2008)." 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 201281/S-002.**" Approval of this submission by FDA is not required before the labeling is used.

## **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 Raymond Chiang, Regulatory Project Manager, at (301) 796-1940.

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

### ENCLOSURES:

Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MARY H PARKS  
09/25/2012