CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

201281Orig1s000

Trade Name: JENTADUETO

Generic Name: linagliptin and metformin hydrochloride

Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc.

Approval Date: January 30, 2012

Indications: a dipeptidyl peptidase-4 (DPP-4) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201281

NDA APPROVAL

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

Dear Ms. Collette:

Please refer to your New Drug Application (NDA) dated and received January 19, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for linagliptin and metformin tablets (2.5 mg/500 mg, 2.5 mg/850 mg and 2.5 mg/1000 mg).

We acknowledge receipt of your amendments dated January 28, March 11, April 12, 19 and 27, May 19, June 1 and 13, July 1 and 27, August 3, 17 and 26, September 1, 15 and 21, November 1 (2), 3, 7, 8 and 30, 2011, and January 17, 2012. The November 30, 2011, submission constituted a complete response to our action letter dated November 16, 2011. We also acknowledge receipt of your email dated January 27, 2012, that includes the agreed-upon labeling.

This new drug application provides for the use of Jentadueto (linagliptin and metformin fixed-dose combination) tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels submitted on November 8, 2011, 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 "**Final Printed Carton and Container Labels for approved NDA 201281**". Approval of this submission by FDA is not required before the labeling is used.

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

REQUIRED PEDIATRIC ASSESSMENTS

We remind you of your requirements under the Pediatric Research Equity Act (PREA) as stated in the approval letter for NDA 201280 for Tradjenta (linagliptin), dated May 2, 2011:

PMR 1766-1: A randomized, placebo-controlled, dose-finding study under PREA evaluating at least two doses of linagliptin as monotherapy in pediatric patients ages 10 to 16 years (inclusive).

Final Protocol Submission: by November 30, 2011
Trial Completion: by February 28, 2014
Final Report Submission: by August 31, 2014

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