CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

201280Orig1s000

Trade Name: Tradjenta tablets, 5 mg

Generic Name: linagliptin

Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc.

Approval Date: May 2, 2011

Indications: An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201280

NDA APPROVAL

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Maureen Oakes, Pharm.D.
Associate Director, Drug Regulatory Affairs
900 Ridgebury Road, P.O. Box 368
Ridgefield, CT 06877

Dear Dr. Oakes:

Please refer to your New Drug Application (NDA) dated and received July 2, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tradjenta (linagliptin) tablets, 5 mg.

We acknowledge receipt of your amendments dated July 7 and 9, August 2, 3, and 25, September 2, 23, and 30, October 8 and 28, November 1, 12, and 19, and December 1, 17, and 21, 2010; and January 6, 27 (2), 28, and 31, February 4, 7, 11 (2), 14, 16 (2), and 18, March 1 (2), 14, 17, 25, and 29, and April 18, 20, and 29, and May 2, 2011.

This new drug application provides for the use of Tradjenta (linagliptin) 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.

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 March 25, 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*. 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 201280**." Approval of this submission by FDA is not required before the labeling is used.

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

ADVISORY COMMITTEE

Your application for Tradjenta (linagliptin) tablets was not referred to an FDA advisory committee because:

- this drug is not a first-in-class anti-diabetic therapy (two other DPP4-inhibitors are currently marketed);
- the indication sought is based on a well-established efficacy endpoint relied upon for approval of other drugs across the 11 classes of anti-diabetic therapies;
- clinical trials assessing efficacy and safety are typical of diabetes programs evaluated by FDA for approval of other anti-diabetic therapies; and
- no unexpected safety concerns were identified in the nonclinical or clinical development program.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 9 years (inclusive) because the necessary studies are impossible or highly impracticable. This is because there are too few children in this age range with type 2 diabetes mellitus to study.

We are deferring submission of your pediatric studies for ages 10 to 16 years (inclusive) for this application because this product is ready for approval for use in adults and pediatric studies have not been completed.

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