DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202331/S-001

SUPPLEMENT APPROVAL

Takeda Pharmaceuticals North America
Attention: Ms. Beth-Anne Knapp, MBA, RAC
One Takeda Parkway
Deerfield, IL 60015

Dear Ms. Knapp:

Please refer to your Supplemental New Drug Application (sNDA) dated January 13, 2012, received January 13, 2012, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Edarbyclor (azilsartan medoxomil and chlorthalidone) Tablets, 40/12.5 and 40/25 mg.

We acknowledge receipt of your amendment dated February 7, 2012.

This "Prior Approval" supplemental new drug application provides for a change in the carton labeling as follows: the statement "Please see the enclosed Package Insert for important safety and other information, including fetal toxicity boxed warning." has been added to the professional sample display trays.

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 January 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 202331/S-001**." 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, please contact:

Quynh Nguyen, Pharm.D., RAC
Regulatory Health Project Manager
(301) 796-0510

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NORMAN L STOCKBRIDGE
04/10/2012