DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090704

Mylan Pharmaceuticals, Inc.
U.S. Agent for Mylan Laboratories Limited
Attention: Shane Shupe
Senior Manager, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on June 25, 2008, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Candesartan Cilexetil and Hydrochlorothiazide Tablets, 16 mg/12.5 mg, 32 mg/12.5 mg and 32 mg/25 mg.[1]

Reference is also made to the tentative approval letter issued by this office on August 9, 2011, and to your amendments dated August 30, November 12, and November 14, 2012.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Candesartan Cilexetil and Hydrochlorothiazide Tablets, 16 mg/12.5 mg, 32 mg/12.5 mg and 32 mg/25 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Atacand-HCT Tablets of AstraZeneca. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, AstraZeneca's Atacand-HCT Tablets, is subject to periods of patent protection. The following unexpired patents and expiration dates are currently listed in the agency's publication titled Approved

[1] The 32 mg/25 mg strength was not included in the original submission of this ANDA. An amendment for this strength was received on March 6, 2009.

Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
5,534,534 (the '534 patent)	January 9, 2014*
5,721,263 (the '263 patent)	February 24, 2015
5,958,961 (the '961 patent)	June 6, 2014

*pediatric exclusivities added

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Candesartan Cilexetil and Hydrochlorothiazide Tablets, 16 mg/12.5 mg, 32 mg/12.5 mg and 32 mg/25 mg, under this ANDA. You have notified the agency that Mylan Laboratories Limited (Mylan) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of any patent was brought against Mylan within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Candesartan Cilexetil and Hydrochlorothiazide Tablets, 16 mg/12.5 mg, 32 mg/12.5 mg and 32 mg/25 mg. As a first applicant, Mylan was eligible for 180 days of generic drug exclusivity for all three strengths. The Agency has determined, however, that (b)(4) has forfeited its eligibility for 180-day exclusivity with respect to the 16 mg/12.5 mg and 32 mg/12.5 mg strengths because Mylan failed to obtain tentative approval of these strengths within 30 months after the date on which the ANDA for these strengths was filed.[2] See section 505(j)(5)(D)(i)(IV) of the Act. Mylan retains its eligibility for 180 days of generic drug exclusivity with respect to the 32 mg/25 mg strength. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,

[2] Mylan's ANDA 090704 was received (filed) on June 25, 2008. This submission covered the 16 mg/12.5 mg and 32 mg/12.5 mg strengths. 30 months from June 25, 2008, was December 25, 2010. An amendment for the 32 mg/25 mg strength was received on March 6, 2009; 30 months from that date was September 6, 2011. ANDA 090704 was tentatively approved on August 9, 2011.

The agency finds that Mylan's failure to obtain tentative approval of the 16 mg/12.5 mg and 32 mg/12.5 mg strengths within 30 months was not caused by a change in or a review of the requirements for approval, nor was a related citizen petition submitted that was subject to section 505(q) of the Act. Mylan's claim, made in a submission dated October 29, 2012, that its failure to obtain tentative approval within 30 months was caused by such a change or review is not supported by the record.

will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required).

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

/s/

GREGORY P GEBA
12/04/2012