



NDA 20-838

AstraZeneca L.P.
Attention: Darci L. Bertelsen
Associate Director, Regulatory Project Management
1800 Concord Pike
Wilmington, DE 19850-5437

Dear Ms. Bertelsen:

Please refer to your correspondence dated July 8, 2004 and facsimile dated June 4, 2004 requesting changes to the Food and Drug Administration's January 8, 2003 Written Request, and the amended Written Request of May 7, 2004 for pediatric studies for candesartan cilexetil.

We reviewed your proposed changes and are amending the below listed sections of the Written Request. All other terms stated in our Written Request issued on January 8, 2003 remain the same.

We are amending the "Format of reports to be submitted" section of your Written Request, which states the specific information on racial and ethnic minorities to be included in the final study report in accordance with Section 18 of the BPCA. Please note that we are changing the word "must" to "should" twice. All other terms stated in our original Written Request or any subsequent amendments remain the same.

Format of reports to be submitted:

In addition, the reports are to include information on the representation of pediatric patients of ethnic and racial minorities. All pediatric patients enrolled in the study(s) **should** be categorized using one of the following designations for race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander or White. For ethnicity one of the following designations **should** be used: Hispanic/Latino or Not Hispanic/Latino.

Submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, "**PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY**" in large font, bolded type at the beginning of the cover letter of the submission. Notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, "**PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES**" in large font, bolded type at the beginning of the cover letter of the submission.

Submit reports of the studies as a **supplement to an approved NDA** with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, clearly mark your submission "**SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED**" in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. In addition, send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **“PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES”** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

If you have any questions please call:

Cheryl Ann Borden, MSN, R.N., CCRN, CCNS
Regulatory Health Project Manager
(301) 594-5412.

Sincerely,

{See appended electronic signature page}

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

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/s/

Norman Stockbridge
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