

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**19-777/S-044**

**Chemistry Review(s)**

<b>CHEMIST'S REVIEW</b>	<b>1. ORGANIZATION</b> HFD-110/810	<b>2. NDA Number</b> 19-777
<b>3. Name and Address of Applicant (City &amp; State)</b> AstraZeneca UK Limited, Macclesfield, Cheshire, England : US Agent – AstraZeneca Pharmaceuticals LP		<b>4. Supplement(s) Number(s) Date(s)</b> SE5-044 11/2/01
<b>5. Drug Name</b> Zestril	<b>6. Nonproprietary Name</b> lisinopril	<b>7. Amendments - Dates</b>
<b>8. Supplement Provides For. a request for a pediatric exclusivity determination</b>		
<b>9. Pharmacological Category</b> Angiotensin converting enzyme inhibitor	<b>10. How Dispensed</b> Rx	<b>Related NDAs: NDA 19-588/SE5-043 (9/24/01) for a common type of change and detailed review notes.</b>
<b>12. Dosage Form(s)</b> TCM	<b>13. Potencies 5, 10, 20, 30, &amp; 40 mg</b>	
<b>14. Chemical Name and Structure:</b> PRINIVIL® (Lisinopril), a synthetic peptide derivative, is an oral long acting angiotensin converting enzyme inhibitor. Lisinopril is chemically described as (S)-1-[N <sup>z</sup> -(1-carboxy-3-phenylpropyl)-L-lysyl]-L-proline dihydrate. Its empirical formula is C <sub>21</sub> H <sub>35</sub> N <sub>3</sub> O <sub>6</sub> ·2H <sub>2</sub> O and its structural formula is 		
<b>26. Comments</b> This supplement deals with an alternate suspension drug product formulation for use in hypertensive pediatric patients. This submission is cross-referenced to the related submission, NDA 19-588/S-043 (9-24-02), and its Chemistry Review dated 7/11/02 for the common CMC evaluations involved.		
<b>17. Conclusions and Recommendations:</b> This supplement may be approved from the standpoint of chemistry, manufacturing and controls.		
<b>18. REVIEWER</b>		<b>FILE NAME: KKKSE5-044(11-2-01)TOKS</b>
<b>Name</b> Stuart Zimmerman, Ph.D.	<b>Signature</b> 	<b>Date Completed</b> 7/11/02

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/s/

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