

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-584/S-005**

**CHEMISTRY REVIEW(S)**

<b>Chemistry Review #1</b>	<b>1. Division</b> HFD-550	<b>2. NDA Number</b> 20-584
<b>3. Name and Address of Applicant</b> Wayeth-Ayerst Laboratories P.O.Box 8299 Philadelphia, PA 19101	<b>4. Supplement Number:</b> SE5-005 <b>Letter Date:</b> 10/12/99 <b>Stamp Date:</b> 10/12/99 <b>Due Date :</b> 8/11/00	
<b>5. Name of Drug</b> Lodine <sup>®</sup> XL Tablets	<b>6. Nonproprietary Name</b> Etodolac Extended Release Tablets	
<b>7. Supplement Provides for:</b> Clinical Trials in Pediatric Patients with Juvenile Rheumatoid Arthritis		<b>8. Amendment(s)</b> BC 7/26/00
<b>9. Pharmacological Category</b> Antiinflammatory	<b>10. How Dispensed</b> Rx	<b>11. Related Documents</b>
<b>12. Dosage Form</b> Tablets	<b>13. Potency(ies)</b> 400, 500 and 600 mg	
<b>14. Chemical Name and Structure</b>  See USAN		
<b>15. Comments</b> This is an efficacy supplement for clinical trials in pediatric patients with Juvenile Rheumatoid Arthritis (JRA). Since there is potentially an increase in the use of the API, because of a new patient population, the applicant is required to submit an EA.		
<b>16. Conclusions and Recommendations</b> The applicant has given the required two statements for a categorical exclusion (a) the concentration of the API will be < 1 ppb and (b) to the best of its knowledge no extraordinary circumstances exist, that could effect the environment adversely.  Therefore, from the CMC standpoint, the EA is acceptable.		
<b>17. Name</b> Vispi P. Bhavnagri, Ph.D., Review Chemist	<b>Signature</b> 	<b>Date</b> 8/9/00
<b>Concurrence</b> Mona Zarifa, Ph.D., Acting Chemistry Team Leader		8/9/00