

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**18-553/S005**

***Trade Name:*** Inderal L.A.

***Generic Name:*** Propranol Hydrochloride

***Sponsor:*** Ayerst Laboratories

***Approval Date:*** August 8, 1984

***Indications:*** The treatment of hypertension.

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*APPLICATION NUMBER:*

**18-553/S005**

## CONTENTS

### Reviews / Information Included in this NDA Review.

<b>Approval Letter</b>	<b>X</b>
<b>Approvable Letter</b>	
<b>Labeling</b>	
<b>Summary Review</b>	
<b>Officer/Employee List</b>	
<b>Office Director Memo</b>	
<b>Cross Discipline Team Leader Review</b>	
<b>Medical Review(s)</b>	
<b>Chemistry Review(s)</b>	<b>X</b>
<b>Environmental Assessment</b>	
<b>Pharmacology Review(s)</b>	
<b>Statistical Review(s)</b>	
<b>Microbiology Review(s)</b>	
<b>Clinical Pharmacology/Biopharmaceutics Review(s)</b>	
<b>Risk Assessment and Risk Mitigation Review(s)</b>	
<b>Proprietary Name Review(s)</b>	
<b>Administrative/Correspondence Document(s)</b>	

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**APPROVAL LETTER**

NDA 18-553/S-005

Ayerst Laboratories  
Division of American Home Products Corporation  
Attention: Mr. John R. Rapoza  
685 Third Avenue  
New York, N.Y. 10017

AUG 9 1984


Dear Mr. Rapoza:

Please refer to your supplemental new drug application of June 27, 1984 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inderal (propranolol hydrochloride) L.A. Capsules.

The supplemental application provides for a 36 month expiration date for Inderal L.A. Capsules packaged in unit dose and promotional packages.

We have completed the review of this supplemental application and it is approved. Our letter of April 19, 1983 detailed the conditions relating to the approval of this application.

Sincerely yours,

  
Stewart J. Ehrreich, Ph.D.  
Deputy Director  
Division of Cardio-Renal Drug Products  
Office of Drug Research and Review  
Center for Drugs and Biologics

cc: NYC-DO  
Original NDA

HFN-110

HFN-110/CSO

HFN-83

HFN-110/JWilliams/8-1-84 *J. Williams*  
jg/8-3-84/7560c *8/6/84*

r/d init: SEhrreich/8-2-84

RWolters/8-2-84

APPROVAL

*RWolters*  
*8/7/84*

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**CHEMISTRY REVIEW(S)**

CHEMIST'S REVIEW <small>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</small>		1. ORGANIZATION HFN-110	2. NDA NUMBER 18-553
3. NAME AND ADDRESS OF APPLICANT (City and State) Ayerst Laboratories Rouses Point, N.Y. 10017		4. AF NUMBER 19-003	
		5. SUPPLEMENT (S) NUMBER(S)      DATE(S)	
6. NAME OF DRUG Inderal L.A. Capsules	7. NONPROPRIETARY NAME Propranolol HCl	S-005	6/27/84
8. SUPPLEMENT(S) PROVIDES FOR: A 36 month expiration date for Inderal L.A. Capsules marketed in both HDPE and blister packages.		9. AMENDMENTS AND OTHER (Reports, etc.) DATES AUG 9 1984	
10. PHARMACOLOGICAL CATEGORY Antihypertensive, antianginal agent	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM (S) Capsules	14. POTENCY (ies) 80, 120 and 160 mg/capsule		
15. CHEMICAL NAME AND STRUCTURE		16. RECORDS AND REPORTS	
		CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS Currently, expiration dates are 24 months for capsules marketed in HDPE bottles and 18 months for blisters.  Data submitted in this report includes 4 batches of samples stored at R.T. in HDPE bottles for 36 months and 3 batches of samples stored at R.T. 62°C and 75% R.H./40°C for 36 months, 12 weeks and 12 weeks respectively. in vinyl blister domes with _____  All data submitted meet the potency spec of _____ Capsules stored 12 weeks in blisters at 62°C showed yellowing of spheroids. This temperature, is however, considered to be excessive. I believe capsules stored at R.T. for 36 months in both HDPE bottles and vinyl blisters, will retain both potency and appearance, without excessive moisture pick up.			
18. CONCLUSIONS AND RECOMMENDATIONS  Ap			
19. REVIEWER			
NAME Jean Williams	SIGNATURE <i>Jean Williams</i>	DATE COMPLETED 7/31/84	
DISTRIBUTION <input type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> REVIEWER <input type="checkbox"/> DIVISION FILE			

18-553-817-100

1   Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling