

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**18-553/S015**

***Trade Name:*** Inderal LA

***Generic Name:*** Propranolol Hydrochloride

***Sponsor:*** Ayerst Laboratories

***Approval Date:*** May 27, 1988

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

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**18-553/S015**

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**APPROVAL LETTER**

32.1  
NDA 18-553/S015

MAY 27 1986

Ayerst Laboratories  
Attention: Mr. John R. Rapoza, M.S.  
685 Third Avenue  
New York, NY 10017-4071

Dear Mr. Rapoza:

Please refer to your March 17, 1986 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Inderal LA (propranolol hydrochloride) Long Acting Capsules.

We also acknowledge receipt of your amendment dated May 8, 1986.

The supplemental application provides \_\_\_\_\_  
\_\_\_\_\_ the coated spheroids \_\_\_\_\_  
\_\_\_\_\_

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.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

*Stewart J. Ehrreich*  
Stewart J. Ehrreich  
Deputy Director  
Office of Drug Research and Review  
Center for Drugs and Biologics

cc:  
~~Original NDA~~  
HFN-110  
HFN-110/CSO  
HFN-83  
HFN-110/JShort/5-11-86  
k1b/5-20-86/05731  
R/D init.: RWolters/5-21-86

APPROVAL

*Wolters*  
*5/23/86*

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**18-553/S015**

**CHEMISTRY REVIEW(S)**

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION	2. NOA NUMBER
		HFN-110	18-553
3. NAME AND ADDRESS OF APPLICANT (City and State)		4. AF NUMBER	
Ayerst Laboratories New York, NY		19-003	
		5. SUPPLEMENT (S)	
		NUMBER(S)	DATE(S)
6. NAME OF DRUG	7. NONPROPRIETARY NAME	S015	3/17/86
Inderal LA	Propranolol Hydrochloride		
8. SUPPLEMENT(S) PROVIDES FOR:		9. AMENDMENTS AND OTHER (Reports, etc.) DATES	
for the coated spheroids		5/8/86	
10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)	
Antihypertensive/Antiangina	<input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		
13. DOSAGE FORM (S)	14. POTENCY (ies)		
CHG	80,120,160 mg		
15. CHEMICAL NAME AND STRUCTURE		16. RECORDS AND REPORTS	
		CURRENT	
		<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
		REVIEWED	
		<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS			
See attachment			
18. CONCLUSIONS AND RECOMMENDATIONS			
The applicant has demonstrated that _____ for the spheroids _____ there- fore this supplement is deemed to be approvable.			
19. NAME		REVIEWER	DATE COMPLETED
James H. Short		<i>James H. Short</i>	MAY 11 1986
DISTRIBUTION	<input checked="" type="checkbox"/> ORIGINAL JACKETS	<input type="checkbox"/> REVIEWER	<input type="checkbox"/> DIVISION FILE

2 Page(s) Withheld

~~\_\_\_~~ § 552(b)(4) Trade Secret / Confidential

\_\_\_ § 552(b)(5) Deliberative Process

\_\_\_ § 552(b)(4) Draft Labeling