

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

18-553/S012

Trade Name: Inderal LA

Generic Name: Propranolol Hydrochloride

Sponsor: Ayerst Laboratories

Approval Date: March 4, 1986

Indications: The treatment of hypertension.

**CENTER FOR DRUG EVALUATION
AND RESEARCH**

APPLICATION NUMBER:

18-553/S012

CONTENTS

Reviews / Information Included in this NDA Review.

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

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

18-553/S012

APPROVAL LETTER

28.1

NDA 18-553/S012

MAR 4 1986

Ayerst Laboratories
Attention: John R. Rapoza, M.S., R.Ph.
695 Third Avenue
New York, NY 10017

Dear Mr. Rapoza:

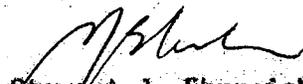
Please refer to your December 30, 1985 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Inderal LA.

The supplemental application provides for a new stability indicating assay procedure utilizing HPLC.

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.

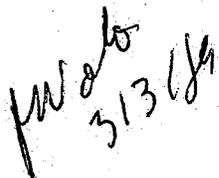
Sincerely yours,

 3/3/86
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:

Original NDA
HFN-110
HFN-110/CSO
HFN-83
HFN-110/JHShort/2/19/86
cb/2/19/86/0790v
R/D init: SEhrreich/2/10/86
RWolters/2/27/86

APPROVAL


Wolters
3/3/86

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

18-553/S012

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 HFN-110	2. NDA NUMBER 18-553
3. NAME AND ADDRESS OF APPLICANT (City and State) Ayerst Laboratories New York, NY		4. AF NUMBER 19-003	
		5. SUPPLEMENT(S) NUMBER(S) DATE(S)	
6. NAME OF DRUG Inderal LA	7. NONPROPRIETARY NAME Propranolol Hydrochloride	S012 S013	12/30/85 12/30/85
8. SUPPLEMENT(S) PROVIDES FOR: S012 provides for the use of a new stability indicating assay utilizing HPLC. S013 provides for a new dosage strength, a 60 mg capsule.		9. AMENDMENTS AND OTHER (Reports, etc.) DATES	
10. PHARMACOLOGICAL CATEGORY Antihypertensive Antianginal	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM(S) CHG	14. POTENCY (ies) 60, 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 <p style="text-align: center;">SEE ATTACHMENT</p>			
18. CONCLUSIONS AND RECOMMENDATIONS S012 is approvable. Additional information is needed before S013 can be approved. The applicant should state if the packaging materials have been approved previously, and if not suitable information should be provided. A review by the Biopharmaceutics Division is needed. The labeling is satisfactory as far as the technical aspects are concerned except that the applicant should affirm that the labels will contain lot numbers and expiration dates as appropriate.			
19. REVIEWER			
NAME James H Short	SIGNATURE <i>James H Short</i>	DATE COMPLETED FEB 6, 1986	
DISTRIBUTION	<input checked="" type="checkbox"/> ORIGINAL JACKET	<input type="checkbox"/> REVIEWER	<input type="checkbox"/> DIVISION FILE CSO

10/18
3/13/85

5 Page(s) Withheld

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

___ § 552(b)(5) Deliberative Process

___ § 552(b)(4) Draft Labeling