

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

18-553/S006

Trade Name: Inderal L.A.

Generic Name: Propranol Hydrochloride

Sponsor: Ayerst Laboratories

Approval Date: March 21, 1985

Indications: The treatment of hypertension.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-553/S006

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	
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)	X

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

18-553/S006

APPROVAL LETTER

NDA 18-553/S-006

MAR 21 1985

Ayerst Laboratories
Attention: Mr. John Rapoza
685 Third Avenue
New York, NY 10017

Dear Mr. Rapoza:

Please refer to your supplemental new drug application of October 24, 1984 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inderal LA (propranolol hydrochloride long acting capsules).

We also acknowledge receipt of your additional communication dated February 20, 1985.

The supplemental application provides for revised physician sample labeling.

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,

R 7 3/20/85

Raymond J. Lipicky, M.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

cc: NYC-DO

Orig. NDA

HFN-83

HFN-110

HFN-232 (with labeling)

HFN-110/CSO

HFN-110/CHenry/3/12/85;3/18/85

sb/3/12/85;3/19/85/0653s

R/D: RWolters/3/13/85

JWilliams 3/12/85

CResnick/3/18/85

CBN 3/19/85

APPROVAL

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

18-553/S006

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT		NDA NUMBER 18-533
		DATE APPROVAL LETTER ISSUED MAR 21 1985
TO: Press Relations Staff (HFI-40)	FROM: ☒ Bureau of Drugs ☐ Bureau of Veterinary Medicine	
ATTENTION Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.		
TYPE OF APPLICATION ☐ ORIGINAL NDA ☒ SUPPLEMENT TO NDA ☐ ABBREVIATED ORIGINAL NDA ☐ SUPPLEMENT TO ANDA		CATEGORY ☒ HUMAN ☐ VETERINARY
TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG Inderal LA (propranolol HCl long acting)		
DOSAGE FORM Capsules		HOW DISPENSED ☒ RX ☐ OTC
ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.) propranolol HCl 80, 120, 160 mg		
NAME OF APPLICANT (Include City and State) Ayerst Laboratories New York, NY 10017		
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY Beta blocker		
COMPLETE FOR VETERINARY ONLY		
ANIMAL SPECIES FOR WHICH APPROVED		
COMPLETE FOR SUPPLEMENT ONLY		
CHANGE APPROVED TO PROVIDE FOR		
Aug		
FORM PREPARED BY NAME Constance Burner Henry <i>Constance Burner Henry</i>		DATE 3/12/85
FORM APPROVED BY NAME Natalia A. Morgenstern		DATE

ORIGINAL

Labeling: 18-553 No'd. 2/21/85

APPROVED BY: OBH 3/1/85

Long Acting  Capsules

CAUTION: Federal law prohibits dispensing without prescription.
USUAL DOSAGE: Read Accompanying Descriptive Literature.

FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.

NOTE: Package not child-resistant.

0471

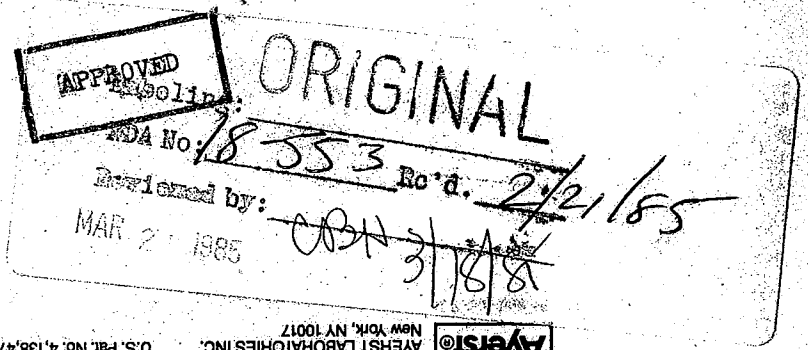
7 CAPSULES/PHYSICIAN'S COMPLIMENTARY PACKAGE

INDERALLA 80 mg
(propranolol hydrochloride)

Just Once Each Day

The appearance of these capsules is a registered trademark of Ayerst Laboratories.

Physician Sample Card



Marketed by
AYERST LABORATORIES INC., New York, NY 10017
Jointly manufactured by Imperial Chemicals Industries PLC,
Macclesfield, Cheshire, SK10 4TF, United Kingdom
and Ayerst Laboratories Inc., New York, NY 10017
U.S. Pat. No. 4,138,475

USUAL DOSAGE: Read Accompanying Descriptive Literature.
FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.
NOTE: Package not child-resistant.
STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C)
PROTECT FROM LIGHT AND MOISTURE
The appearance of these capsules is a registered trademark of Ayerst Laboratories.

0471-47-74

Long Acting  Capsules

INDERAL LA 80_{mg}
(propranolol hydrochloride)

Just Once Each Day

4 CARDS
7 CAPSULES EACH

Physician Sample Carton

APPROVE

Labeling: **ORIGINAL**

Lot No: **18-553** No. d. **2/21/65**

Control No: **CBN 3/18/65**

Long Acting  Capsules

CAUTION: Federal law prohibits dispensing without prescription.
USUAL DOSAGE: Read Accompanying Descriptive Literature.

FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.

NOTE: Package not child-resistant.

0473

7 CAPSULES/PHYSICIAN'S COMPLIMENTARY PACKAGE

INDERAL[®] LA 120_{mg}
(propranolol hydrochloride)

Just Once Each Day

The appearance of these capsules is a registered trademark of Ayerst Laboratories.

Physician Sample Card

APPROVED

Modeling ORIGINAL

FDA No: 18-553 Rec'd. 2/2/85

MAK. Authorized by: CBH3/1/85

Printed in U.S.A.

Ayerst

Marketed by
AYERST LABORATORIES INC.
New York, NY 10017
Jointly manufactured by Imperial Chemicals Industries P.L.C.
Macclesfield, Cheshire SK10 4TF, United Kingdom
and Ayerst Laboratories Inc., New York, NY 10017

U.S. Pat. No. 4,138,475

The appearance of these capsules is a registered trademark of Ayerst Laboratories.

STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C)
PROTECT FROM LIGHT AND MOISTURE

NOTE: Package not child-resistant.

FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.
USUAL DOSAGE: Read Accompanying Descriptive Literature.

0473-47-74



Long Acting Capsules

INDERAL[®] LA 120_{mg}

(propranolol hydrochloride)

Just Once Each Day

4 CARDS
7 CAPSULES EACH

Physician Sample Carton

APPROVED

Labeling: **ORIGINAL**
FDA No. 18-553 No'd. 2/21/85
Reviewed by: CBN 3/1/85

Long Acting  Capsules

CAUTION: Federal law prohibits
dispensing without prescription.
USUAL DOSAGE: Read Accompanying
Descriptive Literature.

FOR FULL PRODUCT INFORMATION,
SEE ACCOMPANYING PACKAGE
CIRCULAR.

NOTE: Package not child-resistant.

0479

7 CAPSULES/PHYSICIAN'S COMPLIMENTARY PACKAGE

INDERAL[®] LA 160_{mg}
(propranolol hydrochloride)
Just Once Each Day

The appearance
of these capsules
is a registered trademark
of Ayerst Laboratories.

Physician Sample Card



ORIGINAL

18-553 Ro'd. 2/21/83

CON 3/1/83

MAR 21 1985

Printed in U.S.A.

Ayerst
AYERST LABORATORIES INC.

New York, NY 10017

U.S. Pat. No. 4,138,475

Marketed by

and Ayerst Laboratories Inc., New York, NY 10017

Jointly manufactured by Imperial Chemicals Industries PLC,
Macclesfield, Cheshire SK10 4TF, United Kingdom

The appearance of these capsules is a registered trademark of Ayerst Laboratories.

PROTECT FROM LIGHT AND MOISTURE
STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C)

NOTE: Package not child-resistant.

FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.

USUAL DOSAGE: Read Accompanying Descriptive Literature.

0479-47-74



Long Acting Capsules

INDERAL[®] LA 160_{mg}
(propranolol hydrochloride)

Just Once Each Day

4 CARDS
7 CAPSULES EACH

Physician Sample Carton

Physician Sample Card

Long Acting Capsules



CAUTION: Federal law prohibits dispensing without prescription.
USUAL DOSAGE: Read Accompanying Descriptive Literature.
FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.
NOTE: Package not child-resistant.

0471
 7 CAPSULES/PHYSICIAN'S COMPLIMENTARY PACKAGE

INDERAL® LA 80 mg
 (propranolol hydrochloride)

Just Once Each Day

The appearance of these capsules is a registered trademark of Ayerst Laboratories.

HOW TO IDENTIFY YOUR MEDICATION

Only **INDERAL® LA** brand of propranolol hydrochloride has this distinctive combination of markings.



Blue capsule with wide white band.

Product name **INDERAL® LA** and dosage strength.

3 narrow white bands.

Jointly manufactured by Imperial Chemicals Industries PLC, Macclesfield, Cheshire SK10 4TF, United Kingdom and Ayerst Laboratories Inc., New York, NY 10017
 Marketed by AYERST LABORATORIES INC., New York, NY 10017



DIRECTIONS FOR USE

STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C)
 PROTECT FROM LIGHT AND MOISTURE
 U.S. Pat. No. 4,139,475

Printed in U.S.A.

APPROVED

MAKING: 16553
 FDA No. 16553
 Approved by: CBN 3/18/85

MAR 2 1985
 ORIGINAL
 MAR 1 1985
 2/21/85

Physician Sample Carton

4 CARDS
7 CAPSULES EACH

INDERAL LA 80^{mg} (propranolol hydrochloride) Just Once Each Day

Long Acting Capsules



0471-47-74

USUAL DOSAGE: Read Accompanying Descriptive Literature.
FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.
NOTE: Package not child-resistant.

STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C)
PROTECT FROM LIGHT AND MOISTURE

The appearance of these capsules is a registered trademark of Ayerst Laboratories.

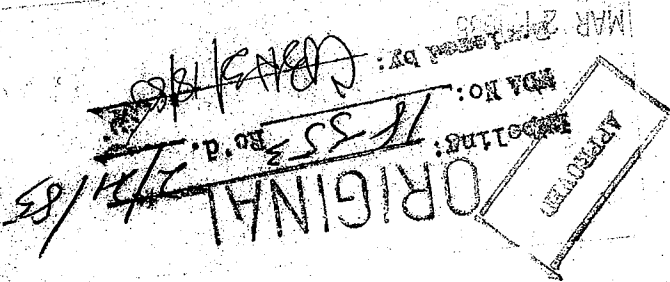
Jointly manufactured by Imperial Chemical Industries PLC,
Macclesfield, Cheshire SK10 4TF, United Kingdom
and Ayerst Laboratories Inc., New York, NY 10017

Ayerst®

Marketed by
AYERST LABORATORIES INC.
New York, NY 10017

U.S. Pat. No. 4,138,475

Printed in U.S.A.



Physician Sample Card

HOW TO IDENTIFY YOUR MEDICATION

Only **INDERAL® LA**
propranolol hydrochloride
has this distinctive combination
of markings.



Blue capsule with
wide white band.

Product name
INDERAL® LA
and dosage strength.

3 narrow white bands.

Jointly manufactured by Imperial Chemicals Industries PLC, Macclesfield, Cheshire SK10 4TF, United Kingdom
and Ayerst Laboratories Inc., New York, NY 10017
Marketed by AYERST LABORATORIES INC., New York, NY 10017



Long Acting

Capsules

CAUTION: Federal law prohibits
dispensing without prescription.
USUAL DOSAGE: Read Accompanying
Descriptive Literature.

FOR FULL PRODUCT INFORMATION,
SEE ACCOMPANYING PACKAGE
CIRCULAR.

NOTE: Package not child-resistant.

0473

7 CAPSULES/PHYSICIAN'S COMPLIMENTARY PACKAGE

INDERAL® LA 120 mg
(propranolol hydrochloride)

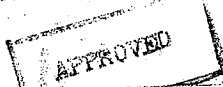
Just On

The appearance
of these capsules
is a registered trad
of Ayerst Laborato

Labeling

FDA No: 18 553

Revised by:



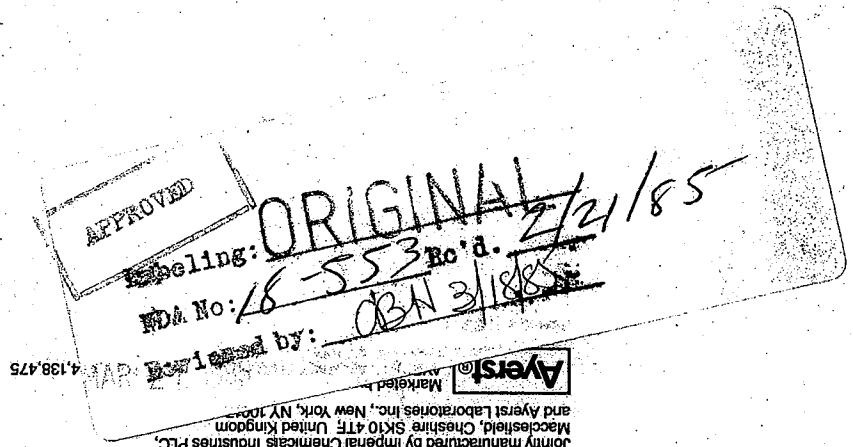
ORIGINAL

MAR 2 1985

DIRECTIONS FOR USE

Printed in U.S.A.

STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C)
PROTECT FROM LIGHT AND MOISTURE
U.S. Pat. No. 4,138,475



The appearance of these capsules is a registered trademark of Ayerst Laboratories.

STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C)
PROTECT FROM LIGHT AND MOISTURE

NOTE: Package not child-resistant.

FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.

USUAL DOSAGE: Read Accompanying Descriptive Literature.

0473-47-74



Long Acting Capsules

INDERAL[®] LA 120_{mg}

(propranolol hydrochloride)

Just Once Each Day

4 CARDS
7 CAPSULES EACH



Physician Sample Card

HOW TO IDENTIFY YOUR MEDICATION

Only **INDERAL® LA**
brand of
propranolol hydrochloride
has this distinctive combination
of markings.



Blue capsule with
wide white band.

Product name
INDERAL® LA
and dosage strength.

3 narrow white bands.

Jointly manufactured by Imperial Chemicals Industries PLC, Macclesfield, Cheshire SK10 4TF, United Kingdom
and Ayerst Laboratories Inc., New York, NY 10017
Marketed by AYERST LABORATORIES INC., New York, NY 10017



0479

7 CAPSULES/PHYSICIAN'S COMPLIMENTARY PACKAGE

Long Acting  **Capsules**

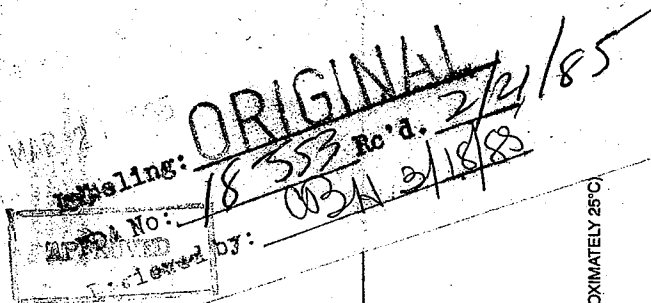
INDERAL® LA 160 mg
(propranolol hydrochloride)

Just Once Each Day

CAUTION: Federal law prohibits
dispensing without prescription.
USUAL DOSAGE: Read Accompanying
Descriptive Literature.

FOR FULL PRODUCT INFORMATION,
SEE ACCOMPANYING PACKAGE
CIRCULAR.

NOTE: Package not child-resistant.



DIRECTIONS FOR USE

STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C).
PROTECT FROM LIGHT AND MOISTURE
U.S. Pat. No. 4,138,475

Printed in U.S.A.

MAR 2 1985
 ORIGINAL
 Tel. No. 18 553 80 8
 Divided by: 2/21/85
 CBA 3/18/85

Printed in U.S.A.
 Ayerst®
 Marketed by
 AYERST LABORATORIES INC.
 New York, NY 10017
 U.S. Pat. No. 4,138,475
 Jointly manufactured by Imperial Chemicals Industries PLC,
 Maclesfield, Cheshire SK10 4TF, United Kingdom
 and Ayerst Laboratories Inc., New York, NY 10017

The appearance of these capsules is a registered trademark of Ayerst Laboratories.
 STORE AT ROOM TEMPERATURE (APPROXIMATELY 25°C)
 PROTECT FROM LIGHT AND MOISTURE
 NOTE: Package not child-resistant.
 FOR FULL PRODUCT INFORMATION, SEE ACCOMPANYING PACKAGE CIRCULAR.
 USUAL DOSAGE: Read Accompanying Descriptive Literature.
 0479-47-74

Long Acting  Capsules

INDERAL[®] LA 160_{mg} (propranolol hydrochloride) **Just Once Each Day**

4 CARDS
 7 CAPSULES EACH

Physician Sample Carton