CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

18-662 / S-057

Trade Name: Accutane

Generic Name: (isotretinoin)

Sponsor: Hoffman La Roche Inc.

Approval Date: January 13, 2006

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-662 / S-057

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-662 / S-057

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-662/S-057

Hoffman-La Roche
Attn.: Christine Hoogmoed
Senior CMC Associate, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

Dear Ms. Hoogmoed:

Please refer to your supplemental new drug application dated September 16, 2005, received September 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ACCUTANE® (isotretinoin) Capsules, 10mg, 20mg, 40mg.

This supplemental new drug application provides for:

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Valerie Jimenez, Regulatory Project Manager, at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hasmukh Patel
1/13/2006 10:41:02 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-662 / S-057

CHEMISTRY REVIEW(S)

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS
HFD-540
Review of Chemistry, Manufacturing, and Controls

NDA#: 18-662	**CHEM.REVIEW#:** 1	**REVIEW DATE:** 08-AUG-2005

SUBMISSION/TYPE	**DOCUMENT DATE**	**CDER DATE**	**ASSIGNED DATE**
Supplement/SCS-057	16-SEP-2005	15-SEP-2005	28-SEP-2005

NAME & ADDRESS OF APPLICANT: Hoffman-La Roche
340 Kingsland Street
Nutley, NJ 07110

Christine Hoogmoed
Senior CMC Associate
Drug Regulatory Affairs
(973)562-5550

DRUG PRODUCT NAME:
Proprietary: Accutane®
Nonproprietary/USAN: Isotretinoin
Therapeutic Class: 1 P

PHARMACOLOGICAL INDICATION: Severe recalcitrant nodular acne

DOSAGE FORM: Capsules
STRENGTHS: 10 mg, 20 mg and 40 mg
ROUTE OF ADMIN: Oral
DISPENSED: __X__ R_x _____ OTC

REMARKS/COMMENTS:

This Supplement for Prior Approval (PAS) was submitted for revised drug product specifications and analytical methods. The following quality attributes, methods and/or acceptance criteria were revised: (1) a new

[redacted]

CONCLUSIONS & RECOMMENDATIONS: **APPROVAL**

The recommendation for this supplemental application is for APPROVAL.

(See attached electronic signature page)

J. S. Hathaway, Ph.D.

cc: Orig. NDA 18-662
/Chem/JSHathaway
/ChemPAL/DLewis
/Chem/BranchChf/HPatel
/ProjMgr/KBhatt

filename: C:\data\MSWordDocs\NDA Reviews\SuppNDAs\18662\N18662r.scs.057.doc

APPROVAL

WITHHOLD 3 PAGE(S)

B4
Chemistry Review

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Steve Hathaway
1/12/2006 03:17:10 PM
CHEMIST

Hasmukh Patel
1/12/2006 03:37:34 PM
CHEMIST