CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

18-662 / S-055

Trade Name: Accutane

Generic Name: (isotretinoin)

Sponsor: Hoffman La Roche Inc.

Approval Date: August 10, 2005

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APPLICATION NUMBER:

18-662 / S-055

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
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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**

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APPLICATION NUMBER:

18-662 / S-055

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-662/S-055

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 February 9, 2005, received February 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ACCUTANE® (isotretinoin) Capsules, 10mg, 20mg, 40mg.

This "Changes Being Effected" supplemental new drug application provides for the addition of a test

[ ]

coli, absent.

We completed our review of this supplemental new drug application. This supplement is approved as of the date of this letter.

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 Kalyani Bhatt, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Norman Schmuff, Ph.D.
Deputy Division Director (Acting),
DNDC III, Office of New Drug Chemistry
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/

Norman Schmuff
8/10/05 02:17:14 PM

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APPLICATION NUMBER:

18-662 / S-055

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-055	09-FEB-2005	10-FEB-2005	18-FEB-2005

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

Christine Hoogmoed
Senior CMC Associate
Drug Regulatory Affairs
(973)562-3550

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 "Special Supplement - Changes Being Effected" (CBE-0) was submitted for the addition of a [illegible]

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
HFD-540/Division File
HFD-540/Chem/JSHathaway
HFD-540/ChemTeamLdr/RSood
HFD-540/ProjMgr/KBhatt

filename: C:\data\MSWordDocs\NDA Reviews\SuppNDAs\18662\N18662r.scs.055.doc

APPROVAL

WITHHOLD 1 PAGE(S)

B4
Chemistry Review

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/s/

Steve Hathaway
8/9/05 07:21:12 AM
CHEMIST
Addition of Microbial Limits testing
For your concurrence

Norman Schmuff
8/10/05 02:03:57 PM
CHEMIST