CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-612 / S-002

Trade Name: Lidoderm Patch™

Generic Name: (lidocaine patch)

Sponsor: Hind Health Care, Inc.

Approval Date: May 26, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-612 / S-002

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:

20-612 / S-002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20612/S-002

MAY 26 1999

Hind Health Care, Inc.
Attention: Larry J. Caldwell, Ph.D.
3707 Williams Road, Suite 101
San Jose, CA 95117-2017

Dear Dr. Caldwell:

Please refer to your supplemental new drug application dated May 13, 1999, received May 14, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lidoderm Patch™ (lidocaine patch) 5% w/w.

This supplemental new drug application provides for a revised specification for the [redacted]

We have completed the review of this supplemental application and it is approved.

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

If you have any questions, contact Victoria Lutwak, Project Manager, at (301) 827-2090.

Sincerely,

Hasmukh B. Patel 5/26/99

Hasmukh B. Patel, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, (HFD-550)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-612 / S-002

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division, HFD-550	2. NDA Number: 20-612
3. Name and Address of Applicant Hind Health Care, Inc. 3707 Williams Road, Suite 101 San Jose, CA 95117-2017	4. Supplement Number: SCS-002	
	Letter Date **05-13-99**	**Stamp Date** **05-14-99**
		Due Date
5. Name of Drug: Lidocain™ Patch	**6. Nonproprietary Name**: Lidocaine	
7. Supplement Provides for: A revised specification for the [redacted]		**8. Amendment(s)**: NA
9. Pharmacological Category	**10. How Dispensed** Rx	**11. Related Documents** NA
12. Dosage Form: Transdermal	**13. Potency(ies)**, 5% w/w	
14. Chemical Name and Structure: See USAN		
15. Supporting Document: **NA**		

16. Comments: Firm provided the following statement:

"Due to problems with the methods and unavailability of a suitable method for the testing, we request deletion of the specification for the [redacted]. We commit to:

[redacted]

The supplemental application did not submit any new information.

17. Conclusions and Recommendations:
This issue was discussed with the Agency on May 11, 1999. This supplement is submitted as per the Agency's suggestion. The supplement is recommended for approval.

18. Name:	**Signature:**	**Date**
Review Chemist	Bart Ho	May 25, 1999
Team Leader:	Hasmukh Patel 5-25-99	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-612 / S-002

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

ORIGINAL

SCS-002

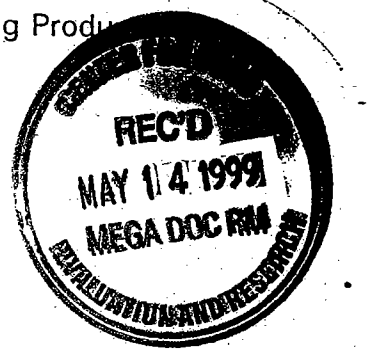
HIND HEALTH CARE, INC.

Larry J. Caldwell, Ph.D.
Consulting Research Director

May 13, 1999

NDA NO 20612 SUPP NO S-002
NDA SUPPL FOR SCS

John Hyde, M.D., Ph.D.
Division of Antiinflammatory, Analgesic, and Ophthalmic Drug Prod
Center for Drug Evaluation Research. (HFD 550)
US Food and Drug Administration
9201 Corporate Blvd
Rockville, MD 20850



Reference: NDA 20-612 SPECIFICATIONS Upper Limit
NDA Supplement 002

Dear Dr. Hyde:

The supplemental application provides for a revised specification for the adhesive upper limit. Due to problems with the methods and unavailability of a suitable method for the testing, we request deletion of the specification for the [redacted] We commit to:

[redacted]

If you have any further questions or comments on this subject, please do not hesitate to call.

Thanks for your help.

Best regards,

Larry J. Caldwell

Larry J. Caldwell, Ph.D.

3707 Williams Road Suite 101, San Jose, CA 95117-2017 TEL.: (408) 615-4140 FAX: (408) 615-4147

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-612/S-002

Hind Health Care, Inc.
3707 Williams Road, Suite 101
San Jose, CA 95117-2017

MAY 21 1999

Attention: Larry J. Caldwell

Dear Mr. Caldwell:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Lidoderm™ (lidocaine USP) Adhesive Patch

NDA Number: 20-612

Supplement Number: S-002

Date of Supplement: May 13, 1999

Date of Receipt: May 14, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on July 13, 1999 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Victoria Wetzel for.

Anthony M. Zeccola
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research