

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER:NDA 20-612**

**MICROBIOLOGY REVIEW(S)**

**REVIEW FOR HFD-550**

**OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805  
Microbiologist's Review #2 of NDA 20-612  
November 25, 1998**

- A. 1. APPLICATION NUMBER:** 20-612
- APPLICANT:** Hind Health Care, Inc.  
165 Gibraltar Court  
Sunnyvale, CA 94089
- 2. PRODUCT NAME:** Lidoderm™ Patch
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Lidocaine patch with adhesive material containing 5% lidocaine. The patch is topically applied only to intact skin.
- 4. METHOD OF STERILIZATION:** non-sterile topical adhesive patch
- 5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:**
- B. 1. DATE OF INITIAL SUBMISSION:** 5/31/96
- 2. DATE OF AMENDMENTS:** 6/1/98 11/19/98 and 11/25/98
- 3. DATE OF CONSULT:** 7/15/98 11/20/98
- 4. ASSIGNED FOR REVIEW:** 9/2/98 11/24/98
- 5. RELATED DOCUMENTS:** NDA 20-612 NA letter of April 17, 1997
- C. REMARKS:** The review package submitted for the 7/15/98 microbiology consult consisted of a 8/30/98 submission labeled as "Response to non-approvable letter (your date April 17, 1997)". The review package also contained copies of the non-approvable letter and draft labeling. The non-approvable letter contained one microbiology deficiency concerning microbial limits of the drug product. However, original NDA 20-612 was not reviewed by an HFD-805 microbiologist. Microbiologist's Review #1 yielded microbial limits deficiencies which were conveyed to the applicant. The applicant's faxed 11/19/98 and 11/25/98 responses are the subject of this review (Microbiologist's Review #2)

**D. CONCLUSIONS:**

The submission is recommended for approval for issues concerning microbiological quality of the drug product.

*NSI*  
*11/25/98*  
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Neal Sweeney, Ph.D.

cc: NDA 20-612  
HFD-550/Division File  
HFD-550/V. Lutwak  
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, November 25, 1998  
R/D initialed by P. Cooney, November 25, 1998

*D. Hussey 11-30-98 for PHC*

REVIEW FOR HFD-550

OCT 22 1998

OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805  
Microbiologist's Review #1 of NDA 20-612  
October 22, 1998

- A. 1. APPLICATION NUMBER: 20-612
- APPLICANT: Hind Health Care, Inc.  
165 Gibraltar Court  
Sunnyvale, CA 94089
2. PRODUCT NAME: Lidoderm™ Patch
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Lidocaine patch with adhesive material containing 5% lidocaine. The patch is topically applied only to intact skin.
4. METHOD OF STERILIZATION: non-sterile topical adhesive patch
5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:
- B. 1. DATE OF INITIAL SUBMISSION: May 31, 1996
2. DATE OF AMENDMENT: June 1, 1998
3. DATE OF CONSULT: July 15, 1998
4. ASSIGNED FOR REVIEW: September 2, 1998
5. RELATED DOCUMENTS: NDA 20-612 NA letter of April 17, 1997
- C. REMARKS: The review package submitted for microbiology consult consisted of a 8/30/98 submission labeled as "Response to non-approvable letter (your date April 17, 1997)". The review package also contained copies of the non-approvable letter and draft labeling. The non-approvable letter contained one microbiology deficiency concerning microbial limits of the drug product. However, original NDA 20-612 was not reviewed by an HFD-805 microbiologist.



**D. CONCLUSIONS:**

The submission is approvable pending resolution of issues concerning microbial limits acceptance criteria for the drug product.

ISI  
10/22/98  
Neal Sweeney, Ph.D.  
PAC

cc: NDA 20-612  
HFD-550/Division File  
HFD-550/V. Lutwak  
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, October 22, 1998  
R/D initialed by P. Cooney, October 22, 1998