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. PHARMACOLOGICAL CATEGORICAL and/or PRINCIPLE INDICATION:

B. 1. DATE OF INITIAL SUBMISSION: 5/31/96


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.

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
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. PHARMACOLOGICAL CATEGORY and 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.

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