

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-005

MICROBIOLOGY REVIEW(S)

REVIEW FOR DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS, HFD-540
OFFICE OF NEW DRUG CHEMISTRY, MICROBIOLOGY STAFF, HFD-805
MICROBIOLOGISTS'S REVIEW No. 1

September 15, 1999

SEP 17 1999

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. NDA No.: 21-005

DRUG PRODUCT NAME: Solarase [diclofenac sodium] gel

APPLICANT:

Hyal Pharmaceutical Corporation
2425 Skymark Avenue
Mississauga, Ontario, Canada
L4WY6

MANUFACTURER:

2. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:**
Non-sterile, topical gel.

3. **METHOD(S) OF STERILIZATION:**
Not applicable; non-sterile, topical dosage form with _____, benzyl alcohol.

4. **PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:**
Treatment of actinic keratotic lesions.

5. **DRUG PRIORITY CLASSIFICATION:** 3 S

B. 1. **DOCUMENT DATE:** Oct 20, 1998
2. **DOCUMENT RECEIVED FOR REVIEW:** July 9, 1999
3. **AMENDMENT:** September 3, 1999
4. **AMENDMENT RECEIVED FOR REVIEW:** September 7, 1999
5. **RELATED DOCUMENTS:**
DMF 10836, July 19, 1999
DMF 11366, July 19, 1999

C. **REMARKS:** The original microbiology consult for NDA 21-005 expressed concerns that the excipient, sodium hyaluronate, was _____ In the current formulation and description for this excipient, the manufacturing method is entirely by _____ There are therefore, no " _____ " to have microbiological concerns about.

D. **CONCLUSION and RECOMMENDATION:** We recommend approval from the microbiology perspective for this topical, _____ drug product with adequate microbial limits. While we are recommending a change to the release specifications for certain microbial limits, there are no microbiological concerns with the manufacture of this product. A commitment to make the changes in specifications on a post-approval basis is acceptable.
See "E. REVIEW NOTES:", below.

CC:
Orig. NDA 21-005
HFD-169/Consult/CKVincent [HFD-805]
HFD-540/MGautam-Basak/DeCamp/KDWhite
Drafted by: CKVincent/09-10-99/

Carol K. Vincent
Review Microbiologist [HFD-805]

Filename: NDA21-005

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