

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20-934**

**MICROBIOLOGY REVIEW(S)**

HFD 540/Cintrea  
AUG 27 1998

REVIEW FOR HFD-540  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-934  
18 August 1998

A. 1. NDA 20-934 BI

APPLICANT: Connetics Corporation  
3400 West Bayshore Road  
Palo Alto, CA 94303

2. PRODUCT NAMES: Betamethasone Valerate Foam 0.1% (BMV Foam)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:  
The product is a topical preparation packaged in an aerosol can.

4. METHODS OF STERILIZATION:  
The product is not a sterile product but, is subject to microbial limits specifications.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:  
The product is indicated for use in treatment of corticosteroid responsive dermatoses.

B. 1. DATE OF INITIAL SUBMISSION: 16 December 1997

2. DATE OF AMENDMENT: 15 July 1998 (Subject of this Review)

3. RELATED DOCUMENTS: DMF DMF IND

4. ASSIGNED FOR REVIEW: 7 August 1998

REMARKS: The application provides for the manufacture of the product at:

CCL Pharmaceuticals, CCL Industries, Ltd.  
9 Arkwright Road, Astmore Industrial Estate  
Runcorn, Cheshire, WA7 1NU - U.K.

**Connetics, NDA 20-934, Betamethasone Valerate Foam 0.1%, Microbiologist's Review #2**

D. CONCLUSIONS: The application is recommended for approval on the basis of microbial quality of the drug product.

IS/

18 August 1998

Paul Stinavage, Ph.D.

JHC 8/27/98

cc: Original NDA 20-934  
HFD-540/O. Cintron  
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 18 August 1998  
R/D initialed by P. Cooney

HFD-540/Cintrom

APR 20 1998

REVIEW FOR HFD-540  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-934  
10 April 1998

A. 1. NDA 20-934

APPLICANT: Connetics Corporation  
3400 West Bayshore Road  
Palo Alto, CA 94303

2. PRODUCT NAMES: Betamethasone Valerate Foam 0.1% (BMV Foam)

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5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:  
The product is indicated for use in treatment of corticosteroid responsive dermatoses.

B. 1. DATE OF INITIAL SUBMISSION: 16 December 1997

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: DMF , DMF IND

4. ASSIGNED FOR REVIEW: 9 January 1998

REMARKS: The application provides for the manufacture of the product at:

CCL Pharmaceuticals, CCL Industries, Ltd.  
9 Arkwright Road, Astmore Industrial Estate  
Runcorn, Cheshire, WA7 1NU - U.K.

**Connetics, NDA 20-934, Betamethasone Valerate Foam 0.1%, Microbiologist's Review #1**

D. CONCLUSIONS: The application is approvable pending resolution of Microbiology concerns.

PSL

Paul Stinavage, Ph.D.

10 April 1998

PAC 4/20/98

cc: Original NDA 20-934  
HFD-540/O. Cintron  
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 10 April 1998  
R/D initialed by P. Cooney

