APPLICATION NUMBER:
22-563

MICROBIOLOGY REVIEW(S)
Product Quality Microbiology Review

26 AUGUST 2010

NDA: 22-563/N-000

Drug Product Name
Proprietary: Sorilux™
Non-proprietary: Calcipotriene Foam, 0.005%

Review Number: 1

Dates of Submission(s) Covered by this Review

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<th>Submit</th>
<th>Received</th>
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<td>18 DECEMBER 2009</td>
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<td>10 MARCH 2010</td>
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<td>28 JUNE 2010</td>
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<td>06 AUGUST</td>
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Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Stiefel Laboratories. Inc
Address: 20 T.W. Alexander Drive
          Research Triangle Park, NC 27709
Representative: Salisa Hauptmann, MPH, RAC
Telephone: 919-990-6133

Name of Reviewer: Robert J. Mello, Ph.D.

Conclusion: The application is recommended for approval from microbiology product quality standpoint.
Product Quality Microbiology Data Sheet

A.  1. TYPE OF SUBMISSION: Original NDA, 505(b)(2)

2. SUBMISSION PROVIDES FOR: Marketing Authorization

3. MANUFACTURING SITE:
   Compounding                  Filling/Packaging
   DPT Laboratories, Ltd.       DPT Laboratories, Ltd.
   307 E. Josephine Street      5303 Distribution Drive
   San Antonio, TX 78215        San Antonio, TX 78218

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Foam (non-sterile), Topical, 0.005%, 60 gram fill into a pressurized aluminum container.

5. METHOD(S) OF STERILIZATION: N/A (Product is non-sterile)

6. PHARMACOLOGICAL CATEGORY: Treatment of plaque psoriasis

B. SUPPORTING/RELATED DOCUMENTS: None

C. REMARKS:
   • The submission is in eCTD format and was available for review via EDR.
   • An Initial Quality Assessment was filed in DARRTS February 16, 2010 by S. Ding. Included were microbiology product quality related comments which included the following:
     a. The applicant states in the NDA that the proposed product failed to meet USP<51> Antimicrobial Effectiveness Test and they also exclude this testing from the drug product specifications. A microbiology consult was requested for these issues.
     b. There was no information on the holding time for the bulk drug product.
   • An information request (IR) was transmitted to the applicant on May 11, 2010 requesting details on the following:
     a. Preservative effectiveness assay methods used during development and for the stability batches
     b. A recommendation that the test be performed in the actual pressurized containers rather than on aliquots dispensed from the containers
     c. Details of test methodologies used for microbial limits testing
     d. Risk assessment or test methodologies to demonstrate that the drug product is free of the objectionable organism B. cepacia
     e. Details of the conduct of the 8-week in-use study to include plate count data
   • Responses to the IR were received in the June 28, 2010 and August 6, 2010 amendments and were incorporated into this review.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability – Recommend Approval

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The formulated drug product is a non-sterile aqueous-based emulsion foam for topical use. It is packaged for multi-dose use in a propellant-pressurized can and is delivered through an actuator/valve system. The propellant is propane/n-butane/isobutene (55%/30%/15%) that is added to the container through the valve system following evacuation of the air from the emulsion-filled container. The drug product does not contain a preservative and is claimed to be self-preserving. However, the results of preservative effectiveness were inconsistent. A consult was submitted from the Division to review the preservative effectiveness methodology and test results.

B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _______________________
   Robert J. Mello, Ph.D.
   Senior Microbiology Reviewer

B. Endorsement Block _____________________________
   John W. Metcalfe, Ph.D.
   Senior Microbiology Reviewer

C. CC Block
   NDA 22-563 file

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Application Type/Number
NDA-22563

Submission Type/Number
ORIG-1

Submitter Name
STIEFEL LABORATORIES INC

Product Name
CALCIPOTRIEN FOAM 0.005%

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT J MELLO
08/27/2010

JOHN W METCALFE
08/27/2010
I concur.