CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202736Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

9 September 2011

NDA: 202-736

Drug Product Name
Proprietary: Sklice Topical Cream
Non-proprietary: ivermectin

Review Number: 2

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
9 September 2011	9 September 2011	-	-

Submission History (for amendments only)

Submit Date(s)	Microbiology Review #	Review Date(s)
04/07/2011	1	24 Aug 2011
04/14/2011	1	24 Aug 2011
07/01/2011	1	24 Aug 2011

Applicant/Sponsor
Name: Topaz Pharmaceuticals
Address: 100 Witmer Road (Suite 280)
Horsham, PA 19044
Representative: Lisa DeLuca, PhD
Telephone: 267-960-3325

Name of Reviewer: James L. McVey

Conclusion: Approve

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Amendment response dated 9/9/2011 to 8/26/2011 information request.

2. SUBMISSION PROVIDES FOR: A new drug application for a topical cream for treatment of head lice (b) (4) on persons 6 month old or older.

3. MANUFACTURING SITE: Product manufacturing and testing will be done at

DPT Laboratories, Ltd.
307 Josephine St.
San Antonio, Texas 78215
FDA Est. Reg. No. 1628114

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: The drug product is a (b) (4) containing 0.5% Ivermectin and (b) (4) water for external application to the hair.

5. METHOD(S) OF STERILIZATION: N.A.

6. PHARMACOLOGICAL CATEGORY: Antiparasitic; a Pediculocide.

B. SUPPORTING/RELATED DOCUMENTS: A right of reference letter for NDA 50-742 (Stromectol) is the basis for 505(b) (1) classification. The Type 2 DMF for the drug substance is 21395. A LOA is included in the application. Not reviewed by product quality microbiology.

C. REMARKS. The amendment dated 7/1/2011 has details of container history and current packaging specifications. Stability data for the lot manufactured because of the first lot failure is included in that amendment.

filename: N202736r2.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – Approve.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – None.

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The drug substance is manufactured by Hovicone PharmaScience Limited. FDA Est. Reg. Number 3002807210.

B. Brief Description of Microbiology Deficiencies – A (b) (4) contamination in the product causes concern that there is adequate control of the manufacturing process. No release testing for microbial limits is proposed. These issues are resolved in the 9/9/2011 amendment.

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

III. Administrative

A. Reviewer's Signature _____
James McVey

B. Endorsement Block _____
Stephen Langille, Ph.D.

C. CC Block - DARRTS

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/s/

JAMES L MCVEY
09/14/2011

STEPHEN E LANGILLE
09/15/2011

Product Quality Microbiology Review

24 August 2011

NDA: 202-736

Drug Product Name
Proprietary: Sklice Topical Cream
Non-proprietary: ivermectin

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
04/07/2011	06/13/2011	06/09/2011	06/16/2011
04/14/2011	-	-	-
07/01/2011	-	-	-

Submission History (for amendments only) N.A.

Applicant/Sponsor
Name: Topaz Pharmaceuticals
Address: 100 Witmer Road (Suite 280)
Horsham, PA 19044
Representative: Lisa DeLuca, PhD
Telephone: 267-960-3325

Name of Reviewer: James L. McVey

Conclusion: Approvable

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original submission. 505(b)(2) converted to 505(b)(1) with Amendments dated 4/14/2011 and 7/1/2011

2. SUBMISSION PROVIDES FOR: A new drug application for a topical cream for treatment of head lice (b) (4) on persons 6 month old or older.

3. MANUFACTURING SITE: Product manufacturing and testing will be done at

DPT Laboratories, Ltd.
307 Josephine St.
San Antonio, Texas 78215
FDA Est. Reg. No. 1628114

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: The drug product is a (b) (4) containing 0.5% Ivermectin and (b) (4) water for external application to the hair.

5. METHOD(S) OF STERILIZATION: N.A.

6. PHARMACOLOGICAL CATEGORY: Antiparasitic; a Pediculocide.

B. SUPPORTING/RELATED DOCUMENTS: A right of reference letter for NDA 50-742 (Stromectol) is the basis for 505(b) (1) classification. The Type 2 DMF for the drug substance is 21395. A LOA is included in the application. Not reviewed by product quality microbiology.

C. REMARKS. The amendment dated 7/1/2011 has details of container history and current packaging specifications. Stability data for the lot manufactured because of the first lot failure is included in that amendment.

filename: N202736r1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – Approvable pending satisfactory responses.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – None.

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The drug substance is manufactured by Hovicone PharmaScience Limited. FDA Est. Reg. Number 3002807210.

B. Brief Description of Microbiology Deficiencies – A (b) (4) contamination in the product causes concern that there is adequate control of the manufacturing process. No release testing for microbial limits is proposed.

C. Assessment of Risk Due to Microbiology Deficiencies – (b) (4) contaminations are hazardous to health especially if the subject has any impairment to his immune system.

III. Administrative

A. Reviewer's Signature _____
James McVey

B. Endorsement Block _____
Stephen Langille, Ph.D.

C. CC Block - DARRTS

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/s/

JAMES L MCVEY
08/24/2011

STEPHEN E LANGILLE
08/24/2011