

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022377Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

5/12/09

NDA: 22-377/N-000

Drug Product Name

Proprietary: (b) (4)™ Auto-Injector

Non-proprietary: sumatriptan succinate

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
7/16/08	7/17/08	8/20/08	8/21/08
4/27/09	4/28/09	N/A	N/A

Submission History (for amendments only): Not applicable

Applicant/Sponsor

Name: King Pharmaceuticals

Address: 501 Fifth St.
Bristol, TN 37620

Representative: Greg Carrier
Vice President, Regulatory Affairs

Telephone: (423) 989-8166

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original new drug application
 - 2. SUBMISSION PROVIDES FOR:** Sterility assurance information associated with an (b) (4) processed drug product.
 - 3. MANUFACTURING SITE:** Meridian Medical Technologies Inc.
2555 Hermelin Dr.
St. Louis, MO
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Sterile liquid injection
 - Subcutaneous
 - 6 mg sumatriptan/0.5 mL
 - 5. METHOD(S) OF STERILIZATION:** Sterile filtration followed by (b) (4) processing.
 - 6. PHARMACOLOGICAL CATEGORY:** Treatment for migraine headaches
- B. SUPPORTING/RELATED DOCUMENTS:** None
- C. REMARKS:** NDA 22-377 is a 505b2 application based on the reference listed drug - Imitrex StatDose (NDA 20-080). A paper desk copy of the application was provided for review. The application was not arranged in common technical document format. An initial quality assessment was entered into DFS on 14-Aug-2008. In it, the Pharmaceutical Assessment Lead states that the issue of sterility assurance for the drug product will be addressed by the Microbiology reviewer. An information request for additional product quality microbiology information was e-mailed to the applicant by the project manager on 4/17/09. The applicant responded to the information request on 4/27/09. A second product quality microbiology information request was e-mailed to the applicant by the project manager on 4/27/09. The applicant responded to this information request by e-mail on 4/30/09. The contents of both of the applicant's responses have been incorporated into this review.

filename: N022377r1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 22-377 is recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
The drug product will be (b) (4) at Meridian Medial Technologies in St. Louis, MO.
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
Stephen E. Langille, Ph.D.
- B. Endorsement Block**
James McVey - Team Leader Name
- C. CC Block**
N/A

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this page is the manifestation of the electronic signature.**

/s/

Stephen Langille
5/12/2009 11:22:04 AM
MICROBIOLOGIST

James McVey
5/12/2009 12:16:16 PM
MICROBIOLOGIST
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 22-377

Applicant: King
Pharmaceuticals

Letter Date: July 16, 2008

Drug Name: Sumatriptan
Succinate Auto-injector

NDA Type: Standard

Stamp Date: July 17, 2008

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		Volume 2
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		Volume 6.
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		Volume 7, p. 351.
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		Volume 5, p. 10.
7	Has the applicant submitted the results of analytical method verification studies?	X		Volume 7, pp. 369-398
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?			Not applicable – no such studies/data was requested.
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The application is not arranged in CTD format but the CMC information is found in volumes 1-8 of 20. The applicant provided paper copies of the pertinent volumes and a CD containing the information for volumes 1-8.

Reviewing Microbiologist

Date

Microbiology Secondary Reviewer/Team Leader

Date

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this page is the manifestation of the electronic signature.**

/s/

Stephen Langille
8/28/2008 01:37:18 PM
MICROBIOLOGIST

James McVey
8/28/2008 02:35:20 PM
MICROBIOLOGIST