CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

200677Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

29 JUNE 2012

NDA: 200677/N-001

Drug Product Name
Proprietary: Signifor®
Non-proprietary: pasireotide

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
17 February 2012	17 February 2012	17 February 2012	23 February 2012

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Novartis Pharmaceuticals Corporation
Address: One Health Plaza, East Hanover, NJ 07936-1080
Representative: Sandip Roy, PhD, Director, DRA
Telephone: (862) 778-0015

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Resubmission of 505(b)(1) NDA

2. SUBMISSION PROVIDES FOR: Marketing Authorization for a parenteral drug product.

3. MANUFACTURING SITE: Novartis Pharma Stein AG
Schaffhauserstrasse
4332 Stein
Switzerland

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile solution in a 1 mL glass ampoule for subcutaneous injection, 0.3, 0.6 and 0.9 mg/mL.

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: Somatostatin analog

B. SUPPORTING/RELATED DOCUMENTS: N/A

C. REMARKS: This was a resubmission after withdrawal. This was an eCTD submission.

filename: N200677R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – This submission is recommended for approval on the basis of product quality microbiology.

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 drug product is (b) (4)

B. Brief Description of Microbiology Deficiencies – N/A

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

III. Administrative

A. Reviewer's Signature _____

Bryan S. Riley, Ph.D.
Senior Review Microbiologist, OPS/NDMS

B. Endorsement Block _____

Stephen E. Langille, Ph.D.
Senior Review Microbiologist, OPS/NDMS

C. CC Block

N/A

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/s/

BRYAN S RILEY
07/03/2012

STEPHEN E LANGILLE
07/03/2012

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 200677 **Applicant:** Novartis **Letter Date:** 17 February 2012

Drug Name: Signifor **NDA Type:** 505(b)(1) **Stamp Date:** 17 February 2012

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		eCTD submission
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		(b) (4)
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
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		CCI studies were provided.
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?	X		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?			N/A
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: N/A

11 April 2012

Bryan S. Riley, Ph.D. Date
Senior Review Microbiologist

Stephen E. Langille Date
Senior Review Microbiologist

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/s/

BRYAN S RILEY
04/12/2012

STEPHEN E LANGILLE
04/12/2012