CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-106

Microbiology Review(s)

Product Quality Microbiology Review
Review for HFD- 510
November 12, 2002

NDA: 21-106 Resubmission to 6/26/01 AE letter.

Drug Product Name
Proprietary: Somavert®
Non-proprietary: pegvisomant for injection
Drug Product Classification: growth hormone receptor agonist

Review Number: 2

Subject of this Review
Submission Date: October 11, 2002, August 29, 2002
Receipt Date: October 15, 2002, August 29, 2002
Consult Date: October 18, 2002
Date Assigned for Review: October 28, 2002

Applicant/Sponsor
Name: Pharmacia & Upjohn
Address: 7000 Portage Road
Kalamazoo, MI 49001-0199

Representative: Satish C. Tripathi, PhD Director, Global Reg. Affairs
Telephone: (269) 833-8095

Name of Reviewer: James L. McVey

Conclusion: The use of Abbot Laboratories to manufacture Somavert® is recommended for approval from a Product Quality Microbiology perspective.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** Class II

2. **SUPPLEMENT PROVIDES FOR:** Response to FDA's approvable letter dated June 26, 2001 and communications with the agency regarding the impact of the changes implemented (phone call referenced in cover letter.)

3. **MANUFACTURING SITE:** Abbott Laboratories
1776 North Centennial Drive
McPherson, KA

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 10 mg, 15 mg and 20 mg single dose vials for subcutaneous injection. A 10 mL vial of Sterile WFI is provided for reconstitution.

5. **METHOD(S) OF STERILIZATION:** [redacted]

6. **PHARMACOLOGICAL CATEGORY:** Growth hormone attachment site inhibitor.

B. **SUPPORTING/RELATED DOCUMENTS:** Microbiologist's Review dated April 20, 2001. Approvable letter dated June 26, 2001.

C. **REMARKS:** The original application was recommended for approval in the first Microbiology review dated April 20, 2001. Because a new Microbiology section was included in the August 29, 2002 submission (Vol. 10), the concern that changes impacting the microbiology section had occurred was raised by the Agency in a FAX dated September 27, 2002. Pharmacia Upjohn identified sections of the deficiency response that may impact the product quality microbiology in the October 15, 2002 amendment.

filename: 21106r2

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is recommended for approval from a product quality microbiology perspective.

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 – See first review.

B. Brief Description of Microbiology Deficiencies – None.

C. Assessment of Risk Due to Microbiology Deficiencies – Minimal risk to safety is expected based on the two product quality microbiology reviews of these submissions.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Review Microbiologist. J.L. McVey
Microbiology Supervisor. P.H. Cooney

C. CC Block
cc:
DFS
HFD- 805/McVey/21106r2

2 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

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

/s/

James McVey
11/25/02 08:11:42 AM
MICROBIOLOGIST

Peter Cooney
11/25/02 08:54:48 AM
MICROBIOLOGIST

REVIEW FOR HFD-510

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #1 of NDA 21-106

April 20, 2001

A. 1. **APPLICATION NUMBER:** 21-106

APPLICANT: Sensus Drug Development Corporation.
98 San Jacinto Blvd., Suite 430
Austin, TX 78701
Phone: 512-487-2000
FAX: 512-487-2049

2. **PRODUCT NAME:** Somavert

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile, lyophilized pegvisomat (10 mg, 15 mg, and 20 mg) for subcutaneous injection. Filled in glass vials.

4. **METHODS OF STERILIZATION:** ———

5. **PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Somavert is indicated for the treatment of patients with acromegaly.

6. **DRUG PRIORITY CLASSIFICATION:** FAST TRACK: Orphan Drug

B. 1. **DATE OF INITIAL SUBMISSION:** 12/22/00

2. **DATE OF CONSULT:** 01/04/01

3. **ASSIGNED FOR REVIEW:** 01/18/01

C. **REMARKS:** The application was submitted only in the electronic format, and was archived at \\CDSESUB1\N21106\N_000\2000-12-22. The product quality microbiology section was located at: \\Cdsesub1\n21106\N_000\2000-12-22\CMC\PRODUCT\MICROBIOL.pdf.

Somavert was referred to as Trovert and B2036-PEG in previous FDA correspondence, and qualified for Orphan Drug designation on 06/24/97.

D. CONCLUSIONS:

The submission is recommended for approval for microbiology issues concerning sterility assurance. Specific comments are provided in section "E. REVIEW NOTES".

Neal Sweeney, Ph.D.

cc: NDA 21-106
HFD-510/Division File
HFD-510/C. King
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, April 20, 2001
R/D initialed by P. Cooney, April 20, 2001

10 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

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

/s/

Neal Sweeney
5/21/01 10:27:38 AM
MICROBIOLOGIST

Peter Cooney
5/21/01 12:27:45 PM
MICROBIOLOGIST