CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-074

MICROBIOLOGY REVIEW(S)

8/8/07

Product Quality Microbiology Review

02 AUG 2007

NDA: 22-074/N-000

Drug Product Name
Proprietary: Somatuline® Autogel
Non-proprietary: Lanreotide Acetate Injection
Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
25 AUG 2006	28 AUG 2006	n/a	n/a
27 OCT 2006	30 OCT 2006	01 SEP 2006	09 NOV 2006
02 FEB 2007	05 FEB 2007	n/a	n/a
27 JULY 2007	30 JULY 2007	n/a	n/a
30 JULY 2007	31 JULY 2007	n/a	n/a

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Beaufour Ipsen Pharma
Address: 24 rue Erlanger
75016 Paris
FRANCE

Representative: Steven R. Scott
Biomeasure Incorporated
27 Maple Street
Milford MA 01757
Telephone: 508-478-0144

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

2. **SUBMISSION PROVIDES FOR:** Marketing Approval

3. **MANUFACTURING SITE:**
Drug Substance: Ipsen Manufacturing Ireland Ltd.,
Blanchardstown Industrial Park,
Blanchardstown
Dublin 15, IRELAND

Drug Product: Ipsen Pharma Biotech
Pare d Activités du Plateau de Signes
Chemin Départemental n0402
83870 Signes, FRANCE

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile Injection, Deep intramuscular injection, 60, 90 and 120mg, single use prefilled polypropylene syringe fitted with a needle.

5. **METHOD(S) OF STERILIZATION:** ——

6. **PHARMACOLOGICAL CATEGORY:** Somatostatin analogue

B. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:**
- The ONDQA PAL Initial Quality Assessment, written 12 DEC 2006 was on file in DFS and was reviewed.
- The submission was a paper technical submission in CTD format. The application was received as a Type M, NDA Pre-submission document with a letter date of 25 AUG 2007 (STAMP DATE of 28 AUG 2007). The official submission stamp date is 30 OCT 2007.
- Provided for review were five of seven bound volumes (white microbiology binders) of Module 3: Quality:
  - Volume 1 of 7
  - Volume 2 of 7
  - Volume 3 of 7
  - Volume 4 of 7
  - Volume 7 of 7

Volume 5 containing the Drug Substance methods validation package and Volume 6 containing the Drug Product methods validation package were not provided for review.

- Also reviewed were three microbiology related NDA amendments: Amendment 002 submitted 02 Feb 2007 (containing the applicant's response to information requests submitted with the 74-day filing communication and in later communications), Amendment 017 dated 27 July 2007 containing responses to additional microbiology questions and Amendment 018 dated 30 July containing a requested change in the wording of the drug product sterility specification for release. The applicant's responses were incorporated into the body of this review.
- Lanreotide Autogel is currently registered in over 40 countries for the treatment of acromegaly and carcinoid syndrome. It received its first marketing authorization in 2001.

Filename: N022074N000R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - The application is recommended for approval from microbiology product quality standpoint.

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 manufactured [redacted]. It is formulated using only the drug substance and water for injection, dispensed into polypropylene syringes and fitted with a [redacted] needle that is covered with a rubber sheath. Filled syringes are packaged into laminated pouches [redacted]. Storage temperature for the drug product is 2°C-8°C.

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.

B. Endorsement Block_____
Stephen E. Langille, Ph.D.

C. CC Block
In DFS

18 Page(s) Withheld

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/s/

Robert Mello
8/8/2007 10:31:49 AM
MICROBIOLOGIST

Recommend approval

Stephen Langille
8/8/2007 11:14:42 AM
MICROBIOLOGIST