APPLICATION NUMBER:
22-074

MICROBIOLOGY REVIEW(S)
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

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<tr>
<th>Letter</th>
<th>Stamp</th>
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<th>Assigned to Reviewer</th>
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<td>25 AUG 2006</td>
<td>28 AUG 2006</td>
<td>n/a</td>
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<td>27 OCT 2006</td>
<td>30 OCT 2006</td>
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<td>30 JULY 2007</td>
<td>31 JULY 2007</td>
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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 Paré 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:
     o Volume 1 of 7
     o Volume 2 of 7
     o Volume 3 of 7
     o Volume 4 of 7
     o 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.
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 using only the drug substance and water for injection, dispensed into polypropylene syringes and fitted with a needle that is covered with a rubber sheath. Filled syringes are packaged into laminated pouches. 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
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