

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-964

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-180

23 NOVEMBER 2007

NDA: 21-964

Drug Product Name

Proprietary: Relistor ~~_____~~, (under review by DMETS) ~~_____~~
Injection

Non-proprietary: Methylnaltrexone Bromide Injection

Drug Product Priority Classification: S1

Review Number:

Dates of Submission(s) Covered by this Review

| Letter | Stamp | Consult Sent | Assigned to Reviewer |
|-------------------|-------------------|-----------------|----------------------|
| March 30, 2007 | March 30, 2007 | May 14, 2007 | May 25, 2007 |

Submission History (for amendments only) -NA

Applicant/Sponsor

Name: Progenics Pharmaceuticals Inc.
Address: Tarrytown, New York 10591
Representative: Alexander W. Rochefort, Senior Director, RA
Telephone: 914-784-1881

Name of Reviewer: Vinayak Pawar, 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:** A new drug for the treatment of opioid-induced constipation.
 3. **MANUFACTURING SITE:** _____
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 20 mg/mL vial for subcutaneous injection, no more than once daily to be injected in _____ volumes based on patient's weight.
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGICAL CATEGORY:** For the treatment of Opioid-Induced Constipation.
- B. **SUPPORTING/RELATED DOCUMENTS:** DMF ✓
- C. **REMARKS:** The consult requests review of the original NDA 21-964 for the drug product Methylbuprenorphine Bromide (The choice of Brand name is under review by DMETS. The entire submission is in an eCTD format. Initial CMC IQA was filed in DFS on May 31, 2007.

filename: C:\my documents\review\NDA\N021964R1

Executive Summary

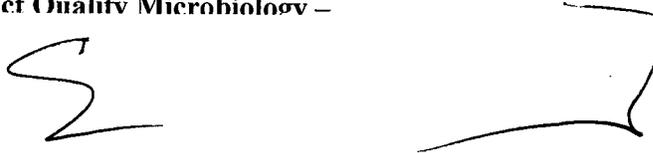
I. Recommendations

A. Recommendation on Approvability -

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -



B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies - Minimal

III. Administrative

A. Reviewer's Signature _____
Vinayak B. Pawar, Ph.D.

B. Endorsement Block _____
Bryan Riley, Ph.D.

C. CC Block
N/A

6 Page(s) Withheld

X § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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

/s/

Vinayak Pawar
11/30/2007 01:12:48 PM
MICROBIOLOGIST

The NDA 21-964 is recommended for approval from microbiology
product quality standpoint.

Bryan Riley
11/30/2007 01:15:00 PM
MICROBIOLOGIST