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RESEARCH**

*APPLICATION NUMBER:*

**22-201**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

18 December 2008

**NDA:** 22-201/N-000

**Drug Product Name**

**Proprietary:** Firmagon.  
**Non-proprietary:** Degarelix for injectable

**b(4)**

**Drug Product Priority Classification:** S.

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

Letter	Stamp	Review Request	Assigned to Reviewer
14 FEB 2008	28 FEB 2008	03 SEP 2008	09 SEP 2008
08 DEC 2008	15 DEC 2008	N/A	N/A

**Applicant/Sponsor**

**Name:** Ferring Pharmaceuticals, Inc.  
**Address:** 4 Gatehall Dr., Third Floor  
Parsippany, NJ 07054  
**Representative:** Ronald T. Hargreaves  
**Telephone:** 973-796-1620

**Name of Reviewer:** John W. Metcalfe, Ph.D.

**Conclusion:** Recommend approval.

## Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** New NDA.
2. **SUBMISSION PROVIDES FOR:** A new drug product.
3. **MANUFACTURING SITE:**  
Sterile Powder for Injection  
 Rentschler Biotechnologie GmbH  
 Erwin Rentschler Str. 21  
 D-88471 Laupheim  
 Germany



b(4)

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Sterile powder \_\_\_\_\_ for injectable : \_\_\_\_\_
  - Subcutaneous injection.
  - 80 mg and 120 mg.

5. **METHOD(S) OF STERILIZATION:** \_\_\_\_\_

b(4)

6. **PHARMACOLOGICAL CATEGORY:** Indicated for treatment of prostate cancer.

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

C. **REMARKS:**

The submission is electronic in the CTD format.

A request for information related to the sterility assurance of the drug product was forwarded to the applicant on 7 October 2008. The information request consisted of the following:

Please provide the following information or reference to its location in the subject NDA:

- The test method used for demonstration of container closure integrity for the sterile powder.
- \_\_\_\_\_

b(4)

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The applicant amended the application with responses to this information request on 08 December 2008. The responses are reviewed in relevant sections of this review.

Appears This Way  
On Original

**File Name:** N022201R1.doc

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**Executive Summary**

**I. Recommendations**

- A. **Recommendation on Approvability** – NDA 22-201/N-000 is recommended for approval on the basis of product quality microbiology.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – Not applicable.

**II. Summary of Microbiology Assessments**

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** - The lyophilized powder is

\_\_\_\_\_

\_\_\_\_\_

b(4)

- B. **Brief Description of Microbiology Deficiencies** – There are no microbiology deficiencies identified.
- C. **Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

**III. Administrative**

A. **Reviewer's Signature** \_\_\_\_\_  
John W. Metcalfe, Ph.D.

B. **Endorsement Block** \_\_\_\_\_  
Stephen Langille, Ph.D.

C. **CC Block**  
In DFS.

13 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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

/s/

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John Metcalfe  
12/18/2008 01:01:01 PM  
MICROBIOLOGIST

Stephen Langille  
12/18/2008 01:14:02 PM  
MICROBIOLOGIST