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RESEARCH**

*APPLICATION NUMBER:*

**22-473**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

23-OCTOBER-2009

**NDA:** 22-473/N-000

**Drug Product Name**

**Proprietary:** REVATIO®

**Non-proprietary:** sildenafil citrate

**Review Number:** 1

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

<u>Letter</u>	<u>Stamp</u>	<u>Review Request</u>	<u>Assigned to Reviewer</u>
16-December-2008	16-December-2009	16-December-2008	18-December-2008
3-August-2009	4-August-2009	N/A	N/A
23-October-2009	23-October-2009	23-October-2009	26-October-2009

**Submission History (for amendments only):** Not applicable

**Applicant/Sponsor**

**Name:** Pfizer Global Pharmaceuticals

**Address:** 235 E. 42<sup>nd</sup> St.

**Representative:** Nancy McKay

**Telephone:** 212-733-4755

**Name of Reviewer:** Stephen E. Langille, Ph.D.

**Conclusion:** Recommended for approval

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## Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUBMISSION: New Drug Application
  2. SUBMISSION PROVIDES FOR: \_\_\_\_\_ **b(4)**  
sildenafil citrate \_\_\_\_\_ injection
  3. MANUFACTURING SITE: Pfizer PGM  
29 Route des Industries  
37530 Poce-sur-Cisse  
Amboise, France
  4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
    - Sterile Solution for Injection
    - Intravenous
    - 0.8 mg/mL
  5. METHOD(S) OF STERILIZATION: \_\_\_\_\_ **b(4)**
  6. PHARMACOLOGICAL CATEGORY: Treatment for pulmonary arterial hypertension
- B. SUPPORTING/RELATED DOCUMENTS: The 17-March-2008 product quality microbiology review of DMF \_\_\_\_\_ is referenced with regard to \_\_\_\_\_ **b(4)**
- C. REMARKS: The application was provided in eCTD format.

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**Executive Summary****I. Recommendations**

- A. Recommendation on Approvability -**  
NDA \_\_\_\_\_ is recommended for approval from the standpoint of product quality microbiology. **b(4)**
- 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 drug product is passed \_\_\_\_\_, and \_\_\_\_\_ **b(4)**
- B. Brief Description of Microbiology Deficiencies -**  
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**  
Not applicable

**III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
Stephen E. Langille
- B. Endorsement Block**  
James McVey – Team Leader
- C. CC Block**  
N/A

10 Page(s) Withheld

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

       § 552(b)(4) Draft Labeling

       § 552(b)(5) Deliberative Process

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22473	ORIG-1	PFIZER INC	REVATIO

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/s/

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STEPHEN E LANGILLE  
10/30/2009

JAMES L MCVEY  
11/02/2009  
I concur.