

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-866

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

14 September 2006

NDA: 21-866

Drug Product Name

Proprietary: Abilify™

Non-proprietary: Aripiprazole

Drug Product Priority Classification:

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Received	Assigned to Reviewer
29 November 2005	30 November 2005	06 Sep 2006	06 September 2006

Applicant/Sponsor

Name: Otsuka Pharmaceutical Co., Ltd.
Address: 2-9 Kanda Tsukasa-cho
Chiyoda-ku Tokyo, 101-8535
Japan

Authorized US Agent

Name: Otsuka Maryland Research
Institute, Inc.
Address: 2440 Research Boulevard
Rockville, MD 20850
Representative: Ms. Angelina Verna
Telephone: 609-818-4063

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

Conclusion: Recommend approval.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA.
 2. **SUBMISSION PROVIDES FOR:** A new drug product.
 3. **MANUFACTURING SITE:**
Bristol-Myers Squibb Manufacturing Company
State Road PR _____
Foreign Trade Zone #7
Mayaguez, Puerto Rico 00680
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Solution.
 - Intramuscular injection.
 - 7.5 mg/mL.
 5. **METHOD(S) OF STERILIZATION:** ~~_____~~
 6. **PHARMACOLOGICAL CATEGORY:** Indicated for the treatment of agitation in schizophrenia and bipolar mania patients.
- B. **SUPPORTING/RELATED DOCUMENTS:** Type ~~DMF~~ *Bristol-Myers Squibb Co.* ~~_____~~ *Located in Mayaguez, PR.*
- C. **REMARKS:** None.

Appears This Way
On Original

File name: N021866R1.doc

Executive Summary**I. Recommendations**

- A. Recommendation on Approvability** – NDA 21-866 is recommended for approval with the following Phase 4 Commitment on the basis of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – Please provide the following as a Phase 4 Commitment: Global Pharmaceutical Technology Report PT-337039-R-232, issued July 15, 2004. Specifically, provide the data which resulted from the subject drug product container closure integrity testing.

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – ~~_____~~
- B. Brief Description of Microbiology Deficiencies** – There are no container closure integrity data provided in either NDA 21-866 or DMF. According to NDA 21-866, these data are found in Global Pharmaceutical Technology Report PT-337039-R-232, issued July 15, 2004.
- C. Assessment of Risk Due to Microbiology Deficiencies** – There is a minimal risk to the sterility assurance of the drug product as a result of this application deficiency.

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Stephen E. Langille, Ph.D.
- C. CC Block**
N/A

7 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/

John Metcalfe
9/15/2006 02:48:11 PM
MICROBIOLOGIST

Stephen Langille
9/19/2006 01:13:26 PM
MICROBIOLOGIST

Appears This Way
On Original