

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-310

MICROBIOLOGY REVIEW(S)

10/31/08

Product Quality Microbiology Review

27 OCTOBER 2008

NDA: 22-310

Drug Product Name

Proprietary: CASODEX

Non-proprietary: bicalutamide

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
6/25/2008	6/25/2008	8/5/2008	8/14/2008

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: AstraZeneca

Address: Alderley Park, Macclesfield, Cheshire, SK104TG, England

Representative: Cindy Lancaster

Telephone: 302-885-1348

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA
2. **SUBMISSION PROVIDES FOR:** An oral suspension for pediatric use of an approved solid oral dosage.
3. **MANUFACTURING SITE:** N/A
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Preserved Oral Suspension
5. **METHOD(S) OF STERILIZATION:** N/A
6. **PHARMACOLOGICAL CATEGORY:** treatment of testotoxicosis
- B. **SUPPORTING/RELATED DOCUMENTS:** DMF — **b(4)**
- C. **REMARKS:** This was an electronic submission in the eCTD format.

filename: N022310R1.doc

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- 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 suspension is prepared by b(4)
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
- B. **Endorsement Block** _____
James L. McVey
Microbiology Team Leader
- C. **CC Block**
N/A

1 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

Withheld Track Number: Microbiology- 1

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

/s/

Bryan Riley
10/31/2008 07:25:50 AM
MICROBIOLOGIST

James McVey
10/31/2008 08:04:16 AM
MICROBIOLOGIST
I concur.