

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-450

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-120

06 JUNE 2002

NDA: 21-450

Drug Product Name

Proprietary: Zomig® Nasal Spray

Non-proprietary: Zolmitriptan

Drug Product Classification: Standard

Review Number: 1

Subject of this Review

Submission Date: 27-Feb-02

Receipt Date: 27-Feb-02

Consult Date: 13-March-02

Date Assigned for Review: 18-March-02

Submission History (for amendments only)

Date(s) of Previous Submission(s): None

Date(s) of Previous Micro Review(s): None

Applicant/Sponsor

Name: iPR Pharmaceuticals, Inc.

Address: P.O. Box 1967, Carolina, PR 00984-1967

Representative: not provided

Telephone: 800-456-3669

U.S. Agent

Name: AstraZeneca Pharmaceuticals, LP

Address: 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803-8355

Representative: Kevin McKenna

Telephone: 302-886-2742

Name of Reviewer: Neal Sweeney, Ph.D.

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
 2. **SUPPLEMENT PROVIDES FOR:** N/A
 3. **MANUFACTURING SITE:** AstraZeneca
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Single dose, non-preserved, zolmitriptan (5 mg. _____) nasal spray for intranasal administration.
 5. **METHOD(S) OF STERILIZATION:** Non-sterile product
 6. **PHARMACOLOGICAL CATEGORY:** Selective inhibitor of 5-HT_{1D} and 5-HT_{1B} receptors. Indicated for the acute treatment of migraine with or without aura in adults.
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** _____
_____ The drug product is not labeled as a sterile product.

filename: 21-450, Zomig (zolmitriptan) nasal spray, iPR Pharmaceuticals.doc

APPEARS THIS WAY
ON ORIGINAL

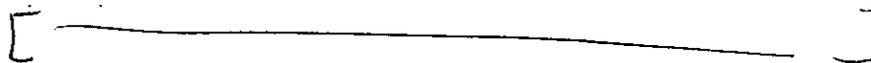
Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – NDA 21-450 is recommended for approval from the standpoint of product quality microbiology. See “Product Quality Microbiology Assessment” section of this review.
- 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 is not labeled as a sterile product.

- B. **Brief Description of Microbiology Deficiencies** – No product quality microbiology deficiencies were identified for this submission.
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Microbiologist: Neal Sweeney
Microbiology Supervisor/Team Leader: Peter Cooney
- C. **CC Block**
cc:
Original NDA 21-450
HFD-120/Division File
HFD-120/L.Y Chen, PM
HFD-805/N. Sweeney/Consult File

7 Page(s) Withheld

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

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

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

/s/

Neal Sweeney
6/17/02 03:29:26 PM
MICROBIOLOGIST

Peter Cooney
6/17/02 04:05:04 PM
MICROBIOLOGIST

APPEARS THIS WAY
ON ORIGINAL