CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
21-450

<u>MICROBIOLOGY REVIEW</u>

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 $5\text{-}HT_{1D}$ and $5\text{-}HT_{1B}$ 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

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