Micro
A. NDA 20-961

PRODUCT NAME: VitraVene™ Injection
fomivirsen sodium intravitreal injection

APPLICANT: Isis Pharmaceuticals, Inc.
2292 Faraday Avenue
Carlsbad, CA USA 92008

DOSAGE FORM: Injectable, 6.6 mg/mL for intravitreal administration
METHOD OF STERILIZATION: Cytomegalovirus Retinitis (CMVR) in AIDS patients

B. INITIAL APPLICATION DATE: April 06, 1998
ASSIGNED FOR REVIEW: April 28, 1998

C. REMARKS: Aseptic fill manufacturing process information included in this submission is the subject of this product quality microbiology review.

D. CONCLUSIONS: The NDA 20-961 which provides for VitraVene™ is approvable from the standpoint of product quality microbiology pending resolution of microbiology issues. Please see section E for Review Notes and section F for "List of Comments and Deficiencies".

Patricia F. Hughes, Ph. D.
Review Microbiologist

cc.: Original NDA 20-961
HFD-160 /Consult File
HFD-160/PFHughes
HFD-550/LGorski/Patel/TSO
HFD-550/Division File
Drafted by PFHughes. 6/17/98
R/D Initialed by PHCooney
REVIEW TO HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST REVIEW OF AN AMENDMENT
August 4, 1998

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PHARMACOLOGICAL CATEGORY: Cytomegalovirus Retinitis (CMVR)
in AIDS patients

B. DATE OF AMENDMENT: July 30, 1998
ASSIGNED FOR REVIEW: July 31, 1998

C. REMARKS: The amendment dated July 30,1998 contains the response to a microbiology deficiency found in the original NDA submission.

D. CONCLUSIONS: The NDA 20-961 which provides for Vitravene™ is recommended for approval from the standpoint of product quality microbiology. Please see section E for Review Notes.

APPEARS THIS WAY ON ORIGINAL

Patricia F. Hughes, Ph. D.
Review Microbiologist

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HFD-160 /Consult File
HFD-160/PHHughes
HFD-550/L.Gorski/Patel/TSO
HFD-550/Division File
Drafted by PHHughes. 8/04/98
R/D Initialed by PHCooney