

Micro

HFD-550 Gorski

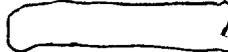
JUN 17 1998

REVIEW TO HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST REVIEW OF AN NDA
JUNE 17, 1998

A. NDA 20-961

PRODUCT NAME: Vitravene™ Injection
fomivirsen sodium intravitreal injection

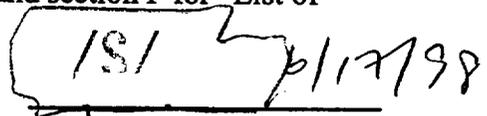
APPLICANT: Isis Pharmaceuticals, Inc.
2292 Faraday Avenue
Carlsbad, CA USA 92008

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

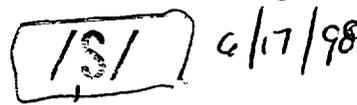
B. INITIAL APPLICATION DATE: April 06, 1998
ASSIGNED FOR REVIEW: April 28, 1998

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

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: [Redacted]
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

[Redacted] 8/4/98

Patricia F. Hughes, Ph. D.
Review Microbiologist

[Redacted] 8/6/98

cc.: Original NDA 20-961
HFD-160 /Consult File
HFD-160/PFHughes
HFD-550/LGorski/Patel/TSO
HFD-550/Division File
Drafted by PFHughes. 8/04/98
R/D Initialed by PHCooney