CMC
DIVISION OF ANTI-INFLAMMATORY, ANALGESIC, AND OPHTHALMIC DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

Type of Review: Consult for HFD-550
Reviewer: Rao V. Kambhampati, HFD-530

NDA #: 20-961

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DATE REVIEWED: 8-4-98

NAME & ADDRESS OF APPLICANT:
ISIS Pharmaceuticals, Inc.
2292 Faraday Avenue
Carlsbad, CA 92008

DRUG NAME:
Proprietary: Vitravene™
Nonproprietary: fomivirsen sodium (USAN; INN)

Code Name/#: ISIS 2922
CAS Registry Number: 160369-77-7

PHARMACOLOGICAL CATEGORY:
Antiviral

INDICATION:
CMV retinitis in AIDS patients.

DOSAGE FORM/STRENGTH:
Sterile solution, 6.6 mg/mL

ROUTE OF ADMINISTRATION:
Intravitreal injection

DISPENSED AS:
Rx

CHEMICAL NAME/STRUCTURAL FORMULA:
Molecular Formula: C204H243N63O114P20S20Na20
Molecular Weight: 7122.27 amu for the Na20 salt
6681.59 amu for the protonated form

Nucleotide Sequence:
5'-GCG TTT GCT CTT CTT CTT GCG-3'

Name:
2'-Deoxyguanosyl-(3'-→5') O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxyguanosyl-(3'-→5' O,O-phosphorothioyl)-thymidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxyguanosyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-thymidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxyguanosyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxycytidylyl-(3'-→5' O,O-phosphorothioyl)-2'-deoxyguanosine, 20-sodium salt.
CONCLUSION: From a chemistry, manufacturing & control standpoint, the application is recommended for “Approval”.

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Orig. NDA 20-961
HFD-550/Division File
HFD-550/STso
HFD-550/Gorski
HFD-550/Chambers
HFD-550/Yang
HFD-530/Kambhampati
HFD-830/Chen
HFD-340
HFD-550/Patel

Su C. Tso, Ph.D.
Chemist, HFD-550/830

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8-21-98