

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-191

Microbiology Review(s)

Review for Division of Medical Imaging and Radiopharmaceutical Drug Products, HFD-160
Office of New Drug Chemistry, Microbiology Staff, HFD-805
Microbiologists's Review No. 1

March 15, 2000

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. **NDA No.:** 21-191

DRUG PRODUCT NAME: AF0150 [Imavist™] [perflexane-phospholipid microbubbles] for injection.

APPLICANT:

Alliance Pharmaceutical Corp.
3040 Science Park Road
San Diego, CA 92121

DRUG PRODUCT MANUFACTURER:

Alliance Pharmaceutical Corp
6175 Lusk Blvd.
San Diego, CA 92121

2. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:**

Sterile powder in glass vial with rubber stopper / aluminum seal. Sterile Water For Injection [SWFI] is added at point of use to form liquid for injection.

3. **METHOD(S) OF STERILIZATION:** _____

4. **PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:**
Diagnostic imaging agent; improved delineation of the left ventricular endocardial border.

5. **DRUG PRIORITY CLASSIFICATION:** Standard

B. 1. **DOCUMENT DATE:** October 11, 1999

2. **DOCUMENT RECEIVED FOR REVIEW:** October 28, 1999

3. **COMIS USER FEE DUE DATE:** April 11, 2000

C. **REMARKS:** Although _____ for this drug product and packaging appear to be _____ procedures, the final filled, stoppered, and sealed glass vials are _____

D. **CONCLUSION and RECOMMENDATION:**

We recommend approval of NDA 21-191 from the microbiology prospective for the _____ sterilization process for this drug product. See "E. REVIEW NOTES:", below.

CC:

Orig. NDA 21-191

HFD-160/Consult/CKVincent [HFD-805]

HFD-160/BParker/MSalazar-Driver/THarper-Velazquez

Drafted by: CKVincent/01-31-2000

Revised by: CKVincent/03-15-2000

Filename: C:\CKV99\NDA21191

Carol K. Vincent
Review Microbiologist [HFD-805]

March 15, 2000

CKV
3/14/00

IS/

Redacted 4

pages of trade

secret and/or

confidential

commercial

information