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RESEARCH**

APPLICATION NUMBER:

40334

CHEMISTRY REVIEW(S)

Chemistry Closed

1. CHEMISTRY REVIEW NO. 4

2. ANDA # 40-334

3. NAME AND ADDRESS OF APPLICANT

Gensia Sicor Pharmaceuticals, Inc.
17 Hughes
Irvine, CA 92618

4. LEGAL BASIS FOR SUBMISSION

Accepted by OGD

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Fluorouracil

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

August 31, 1998

Original Submission

September 16, 1998

New Correspondence (revised first page of form 356h submission)

March 31, 1999

Amendment (responding to deficiencies per Chem Review #1)

November 12, 1999

Amendment (responding to deficiencies per Chem Review #2)

November 23, 1999

Labeling Information

*January 5, 2000

Amendment (responding to deficiencies per Chem Review #3)

10. PHARMACOLOGICAL CATEGORY

Antineoplastic

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

NDA for Adrucil® Injection
DMF {
DMF

Pharmacia and Upjohn

DMF
DMF

13. DOSAGE FORM

Injectable

14. POTENCY

50 mg/mL Pharmacy Bulk Packages, (50 mL and 100 mL)

15. CHEMICAL NAME AND STRUCTURE

5-fluoro-2,4(1H,3H)-Pyrimidinedione

For structure, see USP 24, page 738.

16. RECORDS AND REPORTS

N/A

17. COMMENTS

As requested:

- (1) The applicant acknowledged that the microbiologist's review of the submission for sterility assurance is pending.
- (2) The applicant acknowledged that an acceptable compliance evaluation is necessary for approval.

18. CONCLUSIONS AND RECOMMENDATIONS

Chemistry closed. Microbiology review is pending.

19. REVIEWER:

IS
Shirley S. Brown

DATE COMPLETED:

January 21, 2000
January 21, 2000

*FER FOR acceptable 2/7/00.
Micro acceptable on 2/16/00
by Enser/Fanning covering
amendment of 2/9/00.
IS
2/17/00*

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Chem 4