CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74511

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO 4

2. ANDA 74-511

3. NAME AND ADDRESS OF APPLICANT

Akorn, Inc.
P.O. Box 1220
Decatur, IL 62525

4. LEGAL BASIS FOR SUBMISSION

Akorn, Inc. certifies that Vasocidin is not entitled to a period of marketing exclusivity under section 505 (j)(4)(D)

The basis of the Akorn proposed ANDA for Sulster (Sulfacetamide Sodium 10% and Prednisolone Sodium Phosphate 0.25% Ophthalmic Solution), is the approved, reference listed drug, Vasocidin, the subject of NDA 18-988, held by Ciba Vision. The NDA is for Sulfacetamide Sodium 1mg & Prednisolone Sodium Phosphate 0.25 mg Ophthalmic solution, an ophthalmic steroid/anti-infective combination and was approved on August 26, 1988.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

Sulster

7. NONPROPRIETARY NAME

Sulfacetamide Sodium 10% and Prednisolone sodium phosphate 0.25% Ophthalmic Solution.

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

N/A

9. AMENDMENTS AND OTHER DATES:

Original 6/24/1994
Amendment 8/10/1994
Amendment 6/7/1995
Amendment 5/17/96
Amendment 7/2/96

10. PHARMACOLOGICAL CATEGORY

Corticosteroid-responsive inflammatory ocular conditions

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF's

13. DOSAGE FORM

Solution

14. POTENCY

Sulfacetamide Sodium 10%
prednisolone Sodium Phosphate 0.25%

15. CHEMICAL NAME AND STRUCTURE

Pregna-1,4-diene-3,20-dione, 11,17-dihydroxy-21-(phosphonooxy),-disodium salt,
(11B)-Acetamide, N-[(4-aminophenyl)sulfonyl]-monosodium salt, monohydrate.

16. RECORDS AND REPORTS

17. COMMENTS

The sterility assurance is acceptable 7/17/95.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER: DATE COMPLETED:

Nashed E. Nashed, Ph.D. 7/22/96

Supervisor:Paul Schwartz, Ph.D. 7/22/96