

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74511

APPROVAL LETTER

ANDA 74-511

JUL 30 1996

Akorn, Inc.
Attention: Jairaj U. Mehta
P.O. Box 1220
Decatur, IL 62525

Dear Sir:

This is in reference to your abbreviated new drug application dated June 24, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Sulster (Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution, 10%/ eq. 0.23% phosphate).

Reference is also made to your amendments dated May 17 and July 2, 1996.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic solution, 10%/eq. 0.23% phosphate, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Vasocidin Ophthalmic Solution of Ciba Vision Ophthalmics.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/

7/30/96

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Research and Review

cc: ANDA 74-511
ANDA 74-511/Division File
Field Copy
HFD-600/Reading File
HFD-82
HFD-8/P.Savino
HFD-610/J.Phillips

Endorsement:

HFD-627/N.Nashed, Ph.D. 7/22/96 *7/30/96*
HFD-627/P.Schwartz, Ph.D. 7/22/96 *7/24/96*
HFD-620/K.Muhvich, Ph.D. 7/14/96 *7/3/96*
HFD-613/L.Golson 6/12/96 *7/25/96*
HFD-613/J.Grace for A.Vezza 6/14/96 *7/20/96*
HFD-617/R.West 7/24/96 *7/30/96*
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F/T bu MM July 25, 1996

APPROVAL LETTER

7/30/96