CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 65-024

APPROVAL LETTER

ANDA 65-024

JUL 30 2004

Altana Inc.
Attention: Audrey Zaweski
60 Baylis Road
Melville, NY 11747

Dear Madam:

This is in reference to your abbreviated new drug application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Gentamicin Ophthalmic Ointment USP, 0.3%. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated August 7, 2002; June 12, June 13, July 1, and December 15, 2003; and January 21, April 2, May 7, June 28, and July 30, 2004.

We note that the reference listed drug product (RLD) upon which you originally based this application, Garamycin Ophthalmic Ointment, 0.3%, of Schering Corporation (Schering), is no longer being market in the United States. Thus, the agency has relocated Schering's Garamycin Ophthalmic Ointment, 0.3%, to the Discontinued section of the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book". However, the agency has made the determination that Garamycin Ophthalmic Ointment, 0.3% was not withdrawn from sale for reasons of safety or effectiveness. This determination, which will be announced in the Federal Register, allows the agency to approve ANDAs for the discontinued drug product.

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 Gentamicin Ophthalmic Ointment USP, 0.3% to be bioequivalent and, therefore, therapeutically equivalent to the

listed drug (Gentamicin Ophthalmic Ointment USP, 0.3%, of Akorn Inc.).

Under Section 506A of the Act, 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 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Robert Lee /for 1/30/2004

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 65-024
Division File
Field Copy
HFD-610/R. West
HFD-330
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HFD-643/M.Shih/ 7/8/04
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HFD-613/L.Golson/ 7/12/04
HFD-600/M.Stevens-Riley/ 7/14/04
HFD-600/N.Sweeney/ 7-14-04

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F/T by: RTN/7/7/04

APPROVAL ~PACT_AP~

Concur satisfactory.
Lloyd Belcher
7/29/04.
S/E determination for
RLD withdrawal from market