CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-958

TENTATIVE APPROVAL LETTER

ANDA 76-300

FEB 27 2003

Altana Inc.
Attention: Robert J. Anderson, Esq.
60 Baylis Road
Melvile, NY 11747

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 22, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fluticasone Propionate Ointment, 0.005%.

Reference is also made to your amendments dated July 29, July 30, September 30, October 18, November 4, November 5, November 19, and November 20, 2002; and February 5, 2003.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Although we are unable to grant final approval at this time because the reference listed drug product (RLD) is subject to a period of patent protection as discussed below. Therefore, the application is **tentatively approved.** This tentative approval is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities (cGMPs) used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application, Cutivate Ointment, 0.005% of GlaxoSmithKline, is currently subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the Orange Book, U.S. Patent 4,335,121 (the '121 patent) was due to expire on November 14, 2003. Your application contains a paragraph III certification to the '121 patent under Section

505(j)(2) (A)(vii)(III) of the Act. This certification states that you will not market this drug product prior to the expiration of the patent. However, the expiration of the '121 patent has effectively been extended by an additional 6 months of marketing exclusivity under Section 111 of Title I of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The Modernization Act created section 505(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505(A) permits certain applications to obtain an additional six months of marketing exclusivity (pediatric exclusivity) if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population. GlaxoSmithKline has submitted such information to the agency. The agency has determined that the submitted information meets the criteria stated in the statute and has granted GlaxoSmithKline 6 months of additional marketing exclusivity with respect to the '121 patent. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the '121 patent has expired, i.e., currently May 14, 2004.

In order to reactivate this application prior to final approval, please submit a MINOR AMENDMENT - FINAL APPROVAL REQUESTED. This amendment should be submitted 60 to 90 days prior to the date you believe the application will be eligible for final approval. The amendment should state the legal/regulatory basis for approval, and it should identify changes, if any, in the conditions under which the product was tentatively approved; i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. Note that this amendment should be submitted even if none of these changes were made.

In addition to this amendment, the agency may request at any time prior to the final date of approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

Should you elect to amend this application to provide for such changes prior to final approval, we request that they be categorized as representing either "major" or "minor" changes. The amendment will be reviewed according to OGD policy in effect at the time of receipt.

This drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the Orange Book. Should you believe that there are grounds for issuing the final approval letter prior to May 14, 2004, you should amend your application accordingly.

For further information on the status of this application, or prior to submitting additional amendments, please contact Sarah Ho, R.Ph., Project Manager, (301) 827-5848.

Sincerely yours,

Gary Buehler 2/27/03
Director
Office of Generic Drugs
Center for Drug Evaluation and Research