ANDA 76-067 February 1, 2002

Clay-Park Labs, Inc.
Attention: Candis Edwards
1700 Bathgate Avenue
Bronx, NY 10457

Dear Madam:

This is in reference to your abbreviated new drug application dated December 21, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Mometasone Furoate Ointment USP, 0.1%.

Reference is also made to your amendments dated November 28, December 14, and December 27, 2001.

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. Therefore, the application is **tentatively approved**. This determination 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 (cGMPs) of the facilities used in the manufacture and testing of the drug product). The 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, Elocon Ointment of Schering Corp., is currently subject to a period of patent protection (U.S. Patent No. 4,472,393 – the '393 patent). Your application contains a Paragraph III Certification to the patent under Section 505(j)(2) (A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of the '393 patent. As noted in the agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", the "Orange Book", this patent was to have expired on September 18, 2001. However, this period was extended under Section 111 of the Food and Drug Administration Modernization Act (21 U.S.C.

355a (1997) for an additional 6 months with the granting of pediatric exclusivity to Schering. 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 '393 patent has expired, i.e., currently March 18, 2002.

In order to reactivate your application prior to final approval, please submit an amendment within 30 days. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. In the event no changes were made, an amendment should be submitted documenting that fact. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED. 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 information described above.

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.

Please note that 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 "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to March 18, 2002, you should amend your application accordingly.

At the time you submit any amendments, you should contact Sarah Ho, R.Ph., Project Manager, at 301-827-5848, for further instructions.

Sincerely yours,

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