DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 74-304

AUG 31 1995

RECEIVED

SEP 06 1995

NMC Laboratories, Inc
c/o A.L. Laboratories
Attention: Deborah Winkel
333 Cassell Drive, Suite 3500
Baltimore, MD 21224

Dear Madam,

Reference is made to your abbreviated new drug application dated December 29, 1992, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act for Betamethasone Dipropionate Ointment USP, (Augmented) 0.05% (base).

Reference is also made to your amendments dated July 5 and 20, 1995.

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 that your Betamethasone Dipropionate Ointment USP, (Augmented) 0.05% is bioequivalent and, therefore therapeutically equivalent, to the listed drug (Diprolene^{R} Ointment, 0.05% (base) of Schering Corporation).

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 FDA-2253 at the time of their initial use.

Sincerely yours,

Roger L. Williams, M.D.
Associate Director for Science and Medical Affairs
Center for Drug Evaluation and Research