CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40168

APPROVAL LETTER

ANDA 40-168

AUG 30 1996

Morton Grove Pharmaceuticals, Inc.
Attention: Maurice E. Bordoni
6451 West Main Street
Morton Grove, IL 60053

Dear Sir:

This is in reference to your abbreviated new drug application dated September 20, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Hydrocortisone and Acetic Acid Otic Solution USP, 1%/2%.

Reference is also made to your amendments dated July 17, August 5, and August 12, 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 that your Hydrocortisone and Acetic Acid Otic Solution USP, 1%/2%, is bioequivalent and, therefore, therapeutically equivalent to the listed drug (VoSol® HC of Wallace Laboratories Division of Carter Wallace, Inc.).

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 campaign. 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, at the time of their initial use, be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253.

Sincerely yours,

/S/

Douglas L. Sporn 8/30/96
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 40-168
ANDA 40-168/Division File
Field Copy
HFD-600/Reading File
HFD-82
HFD-8/PSavino
HFD-110/JPhillips

Endorsement:

HFD-627/NNashed/8-14-96 8/16/96
HFD-613/AVezza/8-14-96 8/16/96
HFD-613/LGolson/8-13-96 8/16/96
HFD-627/PSchwartz, PhD/8-14-96 8/16/96
HFD-627/WRussell, PM/8-14-96 8/16/96
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F/T by MM August 15, 1996
APPROVAL LETTER

8/30/96
J. Phillips
E.E.R. - acceptable