CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 17-010

Trade Name: Desonide 0.05% cream

Generic Name: tridesilon

Sponsor: Dome Laboratories.

Approval Date: January 4, 1972

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APPLICATION NUMBER:

NDA 17-010

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APPROVAL LETTER

Our Reference
NDA 17-010

Dome Laboratories
Division of Miles Laboratories, Inc.
Attention: Mr. Charles F. Rayner
West Haven, Connecticut 06516

JAN 4 1972

Gentlemen:

Reference is made to your new drug application dated February 8, 1971 submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for the preparation Tridesilon (desonide) 0.05% Creme.

We also acknowledge receipt of your additional communications dated November 5 and 22, 1971 amending the application.

The application was filed on November 22, 1971.

We have completed the review of this application as amended and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

In addition, we would appreciate your submitting in duplicate, the advertising copy which you intend to use in your immediate or proposed promotional or advertising campaign. Please submit one copy directly to the Division of Drug Advertising with a copy of the package insert and the other to the Division of Anti-Infective Drug Products.

The enclosures summarize the conditions relating to the approval of this application.

Please submit two market packages of the drug when available.

Sincerely yours,

Henry E. Simmons, M.D., M.P.H.
Director
Bureau of Drugs

Enclosures:
Records and Reports Requirement (Reg. 130.13)
Conditions of Approval of NDA

cc: BOS-DO Orig. NDA Dup NDA Trip NDA BD-1 BD-2 BD-100 BD-130
BD-130/Pharmacology RSSobell/DME/sct/11/29/71 CA-226 CA-224 BD-242
BD-22 R/D init. by: DJKertesz 11/24/71