

MAY 7 - 1975

NDA 16-831/S-011

Hoffmann-La Roche, Inc.  
Attention: Edward E. Garcia, Ph.D.  
Nutley, New Jersey 07110

Gentlemen:

Reference is made to your supplemental new drug application of March 20, 1975, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Efudex (fluorouracil) Topical Cream and Solutions.

The supplemental application provides for revised specifications and directions for determining the

We have completed the review of this supplemental application and it is approved. Our letter of July 29, 1970, detailed the conditions relating to the approval of this application.

Sincerely yours,

Merle L. Gibson, M.D.  
Director  
Division of Anti-Infective  
Drug Products  
Bureau of Drugs

cc: NWK-DO

Orig

HFD-610

HFD-140

HFD-140/HCZe11/4/21/75/sjw/4/29/75

R/D init. by: ARCasola/4/23/75

AESmith

APPROVED

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