



Food and Drug Administration
Rockville MD 20857

FILE COPY

July 2, 2001

Deborah L. Therese
Ferndale Laboratories Inc.
780 West Eight Mile Road
Ferndale, MI 48220

Dear Ms. Therese:

Your petition requesting the Food and Drug Administration to make a determination that an abbreviated new drug application (ANDA) is suitable for a topical solution containing 2.5% 5-fluorouracil, was received by this office on 06/29/01. It was assigned docket number 01P-0288/CP 1 and it was filed on 06/29/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,


Gloria Ortega
Dockets Management Branch

01P-0288

ACK 1