

Food and Drug Administration Rockville MD 20857

FILE COPY

July 2, 2001

Deborah L. Theres Ferndale Laboratories, Inc. 780 West Eight Mile Road Ferndale, Michigan 48220

Dear Ms. Theres:

Your petition requesting the Food and Drug Administration to approve an ANDA suitability for a topical cream containing 5% lidocaine, was received by this office on 07/02/01. It was assigned docket number 01P-0291/CP1 and it was filed on 07/02/01. 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,

Helen K. Harris

Dockets Management Branch

ACKI