

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

August 15, 2003

FILE COPY

Dr. Robert A. Jerussi
Jerussi Consulting, Inc.
3311 Midland Road
Fairfax, Virginia 22031

Dear Dr. Jerussi:

Your petition requesting the Food and Drug Administration to make a determination that the Galderma product, Solage containing 2% Mequinol, and 0.01% tretinoin, NDA 20-922 can be formulated as a topical solution with the substitution of Hydroquinone at 4% for the 2% Mequinol and filed as an ANDA referencing Solage, NDA 20-922 as the reference listed drug, was received by this office on 08/12/2003. It was assigned docket number 2003P-0365 and it was filed on 08/13/2003. 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,



Lyle D. Jaffe
Division of Dockets Management

2003P 0365

ACK/