



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

October 4, 2004

Mr. Jerry S. Roth
Hill Dermaceuticals, Inc.
2650 South Mellonville Avenue
Sanford, Florida 32773-9361

Dear Mr. Roth:

Your petition requesting the Food and Drug Administration to not approve any generic equivalent version of the petitioner's proprietary drug product DERMA-SMOOTHIE/FS (fluocinolone acetonide 0.01% topical oil) unless and until ANDA applicants comply with statutory requirements, was received by this office on 10/01/2004. It was assigned docket number 2004P-0448/CP 1 and it was filed 10/01/04. 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
Office of Management Programs

Office of Management

x
x
x
x

Dear x:

Your petition requesting the Food and Drug Administration to
xxxxxxxxxxxxxxxxxxxxxxxxxxxx, was received by this office on 08/12/2004. It was
assigned docket number 2004V-0364/VAR1 and it was filed on 08/12/2004.
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,

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management