



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILE COPY

July 10, 2003

E. Edward Kavanaugh, President
CTFA
1101 17th Street, N.W., Suite 300
Washington, DC 20036-4702

Dear Mr. Kavanaugh:

Your petition requesting the Food and Drug Administration to reconsider and stay an action of certain decisions by the Agency in the Final Monograph for "Skin Protectant Drugs for OTC Human Use" was received by this office on 07/07/2003. It was assigned docket number 1978N-0021/PRC 1 and it was filed on 07/07/2003. 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,

A handwritten signature in cursive script that reads "Lyle D. Jaffe".

Lyle D. Jaffe
Division of Dockets Management

1978N-0021

ACK 2