

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, District of Columbia 20036-4702

Dear Mr. Kavanaugh:

Your petition requesting the Food and Drug Administration to reconsider and stay the action of certain decisions by the Agency in the Final Monograph for "Skin Protectant Drug Products for OTC Human Use" was received by this office on 07/07/2003. It was assigned docket number 1978N-0021P/PRC1 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,

Lyle D. Jaffe

Division of Dockets Management

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