



18 October 2000

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Charles J. Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation
Center of Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No. 78N-0301 Comments No.
CP, AMD2, RPT, AMD6, C86, C92
AMD7, C94, RPT2, SUP4, SUP5,
CP10, CP11, and CP12

Dear Dr. Ganley:

We acknowledge receiving your letter, dated October 3, 2000, that references the Citizen Petition and additional comments filed by Thompson Medical Company in 1981 (Docket No. 78N-0301.) Chattem purchased the over-the-counter products containing trolamine salicylate from Thompson Medical Company in December 1998. We are currently reviewing the points covered in your letter and the clinical records transferred to Chattem during the acquisition of the affected products, Aspercreme® and Sportscreme®.

Chattem intends to provide a more detailed answer to the FDA letter, and therefore, respectfully requests an extension of our response time until November 30, 2000. In that letter, we will also request a meeting with your office to discuss that response and the possibility of Chattem submitting additional clinical data to the Agency on this matter.

Dr. Michael Law in my department is serving as the Chattem contact in this matter, and can be reached at the address listed. His phone number is (423) 821-2037, Extension 370. He may also be reached by electronic mail at mlaw@chattem.com.

We hope this proposal is acceptable to you. We look forward to working with you and your staff to resolve any outstanding issues.

Sincerely yours,

Elaine M. Morefield, Ph.D.
Vice President - Research and Development

cc: Dr. Michael Law
Dockets Management Branch (HFA-305), 3 copies

78N-0301

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