

Memorandum of Telephone Conversation

Date: November 13, 2000

Between: Dr. Michael Law, Chattem, Inc., 1715 West 38th St., Chattanooga, TN 37409
(423) 821-2037 (X370)

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and

Gerald M. Rachanow, Regulatory Counsel, Division of OTC Drug Products, FDA

Subject: Trolamine Salicylate

I called Dr. Law about his company's October 18, 2000 letter to Dr. Charles Ganley. That letter was in response to the Division of OTC Drug Products' letter of October 3, 2000 on trolamine salicylate and identified Dr. Law as the Chattem contact person. The incoming letter is on file in the Dockets Management Branch under Docket No. 78N-0301 as EXT2.

In the letter, Chattem requested an extension of its response time until November 30, 2000 to provide a more detailed answer to the Division's letter, which had requested the company to notify the agency whether it intended to conduct any additional clinical studies. I informed Dr. Law that we considered the statement in the company's letter concerning the possibility of Chattem submitting additional clinical data to the agency on this matter as an indication that the company might conduct additional clinical studies.

I explained that, while the company could comment on the Division's October 3, 2000 letter, that letter and a future letter from the Associate Commissioner for Regulatory Affairs were intended to close out the citizen petitions addressed in those letters and that any future clinical studies/data should be submitted under a new citizen petition. I added that agency review of clinical testing protocols could be handled through feedback procedures without the need for a citizen petition but that the protocol(s) had to be submitted to Docket No. 78N-0301.

I noted that the company stated its intention of requesting a meeting with the Division to discuss issues related to trolamine salicylate. I informed Dr. Law that he should schedule around the upcoming Christmas holiday, before or after, depending when the company was ready. I added that any meeting would be more productive if a proposed clinical protocol was submitted sufficiently far enough in advance to allow adequate time for agency reviewers to evaluate it. I concluded by stating that the company could have until November 30, 2000, to provide its response, or could take longer if the response was part of a package for a meeting. I reminded Dr. Law that any response had to be submitted to the docket (3 copies) and that additional copies sent directly to the Division for meeting attendees would be appropriate.

Dr. Law thanked me for calling him, and the conversation concluded amicably.

Gerald M. Rachanow

Gerald M. Rachanow, P.D., J.D.

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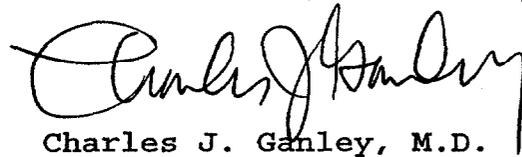
M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: Nov. 21, 2000
FROM: Director
Division of OTC Drug Products, HFD-560
SUBJECT: Material for Docket No. 78N-0301
TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. CP, AMD2, RPT, AMD6, C86, C92, AMD7, C94


Charles J. Ganley, M.D.

RPT2, SUP4, SUP5, CP10, CP11, CP12

Attachment