8263 '01 FEB 28 A9:56

16 February, 2001

CHATTEM

CERTIFIED MAIL

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
c/o Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: Docket No. 78N-0301

Dear Dr. Ganley,

We acknowledge the comments in your letters, dated 03 October and 22 December 2000 regarding the Over-the-Counter (OTC) status of 10% Trolamine Salicylate as an ingredient in a topical drug product. After extensive consultation with experts and a contract laboratory that are experienced with studies in this topic, Chattem, Inc. submits the enclosed study protocol (protocol number: CHA-TEA01-01) to demonstrate that 10% Trolamine Salicylate is an effective ingredient in external analgesic drug products for your review.

We respectfully request that FDA grant a study protocol review meeting after reviewing the study protocol. We have also enclosed a proposed meeting agenda.

Sincerely yours,

Michael Law, Ph.D.
Regulatory Affairs Manager

Enclosures

CHATTEM, INC.
1715 West 38th Street
Chattanooga, TN 37409
(423) 821-2037

78N-0301

PR 4

Proposed Meeting Agenda for Protocol Review

Meeting Date:	Location:	Time:
To be Determined.	To be Determined.	To be Determined.

Participants:

Representatives from FDA
From Chattem, Inc.
Elaine Morefield, Ph.D., Vice President, Research and Development
Michael Law, Ph.D., Regulatory Affairs Manager
William Durkin, Product Safety Manager
From Arnall Golden and Gregory, LLP
Alan Minsk, Esq., Regulatory Counsel
From Clinical Research Laboratories, Inc.
Darcee Strube, Vice President, Clinical Research Operations
From Rutgers University (Statistical Consultant)
J. Richard Trout, Ph.D., Statistical Consultant

Meeting Chair (FDA):
Sponsor Lead: Michael Law, Ph.D.

Introductions:			
	1.	Chair	Opening remarks
	2.	Sponsor	Review meeting objectives

Meeting Objectives:

1. Review the attached protocol for its acceptance as a well-designed study to demonstrate that 10% trolamine salicylate is an effective ingredient in an over-the-counter external analgesic drug product for temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, and sprains.

2. Discuss the usefulness of this model in future studies to demonstrate the effectiveness of ingredients in an over-the-counter external analgesic drug product for temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, and sprains.

Meeting Discussion Items:

	Name of Presenter	Discussion Item	Time Allocated
1.	Michael Law, Ph.D.	Introduction and overview	2 minutes
2.	William Durkin and Darcee Strube	Protocol presentation	10 minutes
3.	FDA	Questions	45 minutes

Summarize Meeting

Discuss Any Necessary Follow-up

Close Meeting

A RANDOMIZED, DOUBLE-BLIND, PARALLEL DESIGN, VEHICLE CONTROLLED STUDY EVALUATING THE EFFICACY OF A TOPICALLY APPLIED CREAM CONTAINING 10% TROLAMINE SALICYLATE IN THE RELIEF OF PAIN AND DISCOMFORT OF OSTEOARTHRITIS OF THE KNEE

Protocol Number:

CHA-TEA01-01

February 12, 2001

Sponsor: Chattem, Inc.
1715 West 38th Street
Chattanooga, TN 37409

Phone: (423) 821-4571
Fax: (423) 825-0203

William Durkin
Manager, Product Safety

A RANDOMIZED, DOUBLE-BLIND, PARALLEL DESIGN, VEHICLE CONTROLLED STUDY EVALUATING THE EFFICACY OF A TOPICALLY APPLIED CREAM CONTAINING 10% TROLAMINE SALICYLATE IN THE RELIEF OF PAIN AND DISCOMFORT OF OSTEOARTHRITIS OF THE KNEE

Protocol Number:

CHA-TEA01-01

February 12, 2001

Protocol Proposal approved by:

William J. Durkin

William Durkin
Manager, Product Safety

2/14/01
Date

TABLE OF CONTENTS

Page

I. Abstract 1
II. Introduction:
A. Background 2
III. Objective
A. Primary Objectives 5
IV. Materials and Methods
A. Study Design 6
B. Study Population 6
C. Study Medication 7
D. Randomization Procedures 8
V. Study Plan
A. Visit 1 – Screening Visit 9
B. Visit 2 – Baseline 9
C. Visit 3 – Day 7 (±1) 10
D. Visit 4 – Day 21 ± 2 Days 10
E. Assessment Scales for Subject and Investigators 11
F. Subject Discontinuation 12
VI. Rescue Medication 13
VII. Statistical Issues
A. Sample Size Justification 14
B. Patient Populations 14
C. Statistical Methods 14
D. General Issues 15
VIII. Adverse Events
A. Definition of an Adverse Event 16
B. Definition of a "Serious" Adverse Event 16
C. Documentation of Adverse Events 17
H. Investigator Report of a Serious Adverse Event 17
IX. Investigator Documentation 18
X. Monitoring 19
XI. References 20
XII. Appendix I 22
XIII. Appendix II 23
XIV. Appendix III 24

Forms
Curriculum vitae

COPYRIGHTED MATERIAL CAN BE VIEWED IN THE DOCKETS MANAGEMENT PUBLIC READING ROOM 5630 FISHERS LANE, ROOM 1061 ROCKVILLE, MD