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The Mentholatum Co., Inc.

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Submitted by Fax

October 28, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: October 14, 2003 Comments to Docket No. 78N-0301; External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph

Dear Sir or Madam:

We wish to assure FDA that The Mentholatum Company does not claim any privilege for anything in the material submitted on October 14, 2003. This information is considered part of the public docket.

Sincerely,

Joyce L. Miller
Director, Regulatory Affairs



The Mentholatum Co., Inc.

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FAX TRANSMITTAL

DATE: October 28, 2003

TO: Latroy Tinch
Dockets Management Branch
Food and Drug Administration
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FAX: 301-827-6870

FROM: Joyce L. Miller
Director, Regulatory Affairs
Ext. 1572

TOTAL PAGES: 2

In response to your telephone contact, please see attached letter regarding The Mentholatum Company's comments to Docket No. 78N-0301 on October 14, 2003.

CONFIDENTIALITY NOTICE

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EST. 1975

Consumer Product Testing Co.

FINAL REPORT

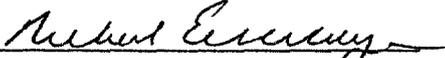
CLIENT: Rohto-Mentholatum
Research Laboratories, Inc.
111 Rock Road
Horsham, Pennsylvania 19044

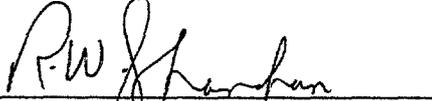
ATTENTION: Meryl Reis

TEST: Repeated Insult Patch Test
Protocol No.: 1.01

TEST MATERIAL: M 2 Patch

**EXPERIMENT
REFERENCE NUMBER:** C02-0163.01


Richard R. Eisenberg, M.D.
Board Certified Dermatologist


Robert W. Shanahan, Ph.D.
Principal Investigator


Joy Frank, R.N.
Study Director

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70 New Dutch Lane • Fairfield, New Jersey 07004-2514 • (973) 808-7111 • Fax (973) 808-7234



Consumer Product Testing Co.

EST. 1975

QUALITY ASSURANCE UNIT STATEMENT

Study No.: C02-0163.01

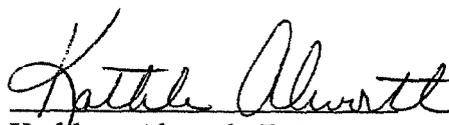
The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of clinical laboratory studies. These studies have been performed with adherence to ICH Guideline E6 for Good Clinical Practice and requirements provided for in 21 CFR parts 50 and 56 and in accordance to standard operating procedures and applicable protocols. The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. The findings of these inspections have been reported to management and the Study Director. All materials and data pertinent to this study will be stored in the Archive Facility at 70 New Dutch Lane, Fairfield, New Jersey, 07004, unless specified otherwise, in writing by the Sponsor.

Date(s) of inspection: March 22, 2002
 April 17, 2002
 April 19, 2002

Senior personnel involved:

OnChi Cheung, B.S. - Quality Assurance Supervisor

Kristin Filak, B.S. - Quality Assurance Associate


Kathleen Alworth, B.A.
Director of Quality Assurance

The representative signature of the Quality Assurance Unit signifies that this study has been performed in accordance with standard operating procedures and study protocol as well as government regulations regarding such procedures and protocols.

Objective: To determine by repetitive epidermal contact the potential of a test material to induce primary or cumulative irritation and/or allergic contact sensitization.

Participants: Six (60) qualified subjects, male and female, ranging in age from 16 to 76 years, were selected for this evaluation. Fifty-six (56) subjects completed this study. The remaining subjects discontinued their participation for various reasons, none of which were related to the application of the test material.

Inclusion Criteria:

- a. Male and female subjects, age 16^a and over.
- b. Absence of any visible skin disease which might be confused with a skin reaction from the test material.
- c. Prohibition of use of topical or systemic steroids and/or antihistamines for at least seven days prior to study initiation.
- d. Completion of a Medical History form and the understanding and signing of an Informed Consent form.
- e. Considered reliable and capable of following directions.

Exclusion Criteria:

- a. Ill health.
- b. Under a doctor's care or taking medication(s) which could influence the outcome of the study.
- c. Females who are pregnant or nursing.
- d. A history of adverse reactions to cosmetics or other personal care products.

Test Material: M 2 Patch

Study Schedule:

<u>Panel #</u>	<u>Initiation Date</u>	<u>Proposed Completion Date</u>	<u>Actual Completion Date</u>
20020111	March 4, 2002	April 11, 2002	April 12, 2002

^aWith parental or guardian consent

Methodology:

The upper back between the scapulae served as the treatment area. Prior to the initiation of this study, the test material was cut into approximately 1" x 1" pieces. The protective film was removed and the test material was applied to the test site. A clear adhesive dressing was then applied to form a semi-occlusive patch.

Induction Phase:

Patches were applied three (3) times per week (e.g., Monday, Wednesday, and Friday) for a total of nine (9) applications. The site was marked to ensure the continuity of patch application. Following supervised removal and scoring of the first Induction patch, participants were instructed to remove all subsequent Induction patches at home, twenty-four hours after application. The evaluation of this site was made again just prior to re-application. If a participant was unable to report for an assigned test day, one (1) makeup day was permitted. This day was added to the Induction period.

With the exception of the first supervised Induction Patch reading, if any test site exhibited a moderate (2-level) reaction during the Induction Phase, application was moved to an adjacent area. Applications are discontinued for the remainder of this test phase, if a moderate (2-level) reaction was observed on this new test site. Applications would also be discontinued if marked (3-level) or severe (4-level) reactivity was noted.

Rest periods consisted of twenty-four hours following each Tuesday and Thursday removal, and forty-eight hours following each Saturday removal.

Challenge Phase:

Approximately two (2) weeks after the final Induction patch application, a Challenge patch was applied to a virgin test site adjacent to the original Induction patch site, following the same procedure described for Induction. The patch was removed and the site scored at the clinic twenty-four and seventy-two hours post-application.

Evaluation Key:

- 0 = No visible skin reaction
- + = Barely perceptible or spotty erythema
- 1 = Mild erythema covering most of the test site
- 2 = Moderate erythema, possible presence of mild edema
- 3 = Marked erythema, possible edema
- 4 = Severe erythema, possible edema, vesiculation, bullae and/or ulceration

Results:

The results of each participant are appended (Table 1).

Observations remained within normal limits throughout the test interval.

Summary:

Under the conditions of this study, test material, M 2 Patch, did not indicate a potential for dermal irritation or allergic contact sensitization.

Table 1
 Panel #20020111

Individual Results

M 2 Patch

Subject Number	24*hr	-----Induction Phase-----									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
1	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	DNC
4	0	+	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0
17	-----DID NOT COMPLETE STUDY-----												
18	0	0	0	0	0	0	0	0 ^m	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0	0
25	0	+	0	0	0	0	0	0	0	0	0	0	0
26	-----DID NOT COMPLETE STUDY-----												
27	0	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch
 DNC = Did not complete study
 m = Additional makeup day granted at the discretion of the clinic supervisor

Table 1
 (continued)
 Panel #20020111

Individual Results

M 2 Patch

Subject Number	24*hr	-----Induction Phase-----									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	24*hr	72 hr	
31	0	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0	0
34	-----DID NOT COMPLETE STUDY-----												
35	0	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0	0*
37	0	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0	0	0
57	0	0	0	0	0	0	0	0	0 ^m	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0	0	0	0	0	0

24* = Supervised removal of 1st Induction and Challenge Patch
 * = Observation conducted 96 hrs. post challenge application. Subject unable to report, as scheduled.
 m = Additional makeup day granted at the discretion of the clinic supervisor

Table 2
Panel #20020111

Subject Data

Subject Number	Initials	Age	Sex
1	TF	49	F
2	AM	28	F
3	DL	39	F
4	RM	31	M
5	WT	31	M
6	LC	50	F
7	EW	18	F
8	MD	27	F
9	CD	68	F
10	JP	39	F
11	JB	29	F
12	ML	41	F
13	MK	58	F
14	CG	43	F
15	FR	59	F
16	JP	19	F
17	LS	31	F
18	RO	24	M
19	PF	76	F
20	LO	16	F
21	GO	47	F
22	CH	47	F
23	AD	49	F
24	SD	25	M
25	CK	42	F
26	OL	68	F
27	BP	50	F
28	TG	36	F
29	SS	24	F
30	CA	22	F

Table 2
(continued)
Panel #20020111

Subject Data

Subject Number	Initials	Age	Sex
31	PS	29	F
32	ME	52	F
33	DL	20	F
34	EM	35	F
35	VR	43	F
36	BF	44	F
37	LA	49	F
38	LN	60	F
39	BC	42	F
40	RG	45	M
41	IN	54	F
42	JG	40	F
43	JA	49	M
44	NR	59	F
45	RR	34	M
46	JP	51	M
47	AG	38	F
48	ET	62	F
49	HS	33	F
50	AR	49	F
51	RM	36	M
52	MD	38	F
53	AF	41	M
54	DF	17	F
55	JR	58	F
56	RS	60	F
57	HD	37	M
58	KD	28	F
59	KH	25	F
60	MH	47	F



ROHTO-MENTHOLATUM
RESEARCH LABORATORIES, INC.

M- 2 Patch

Contains 5% menthol

For Research Purposes Only

2/26/2002 NB 47/197



ROHTO-MENTHOLATUM
RESEARCH LABORATORIES, INC.

M- 2 Patch

Contains 5% menthol

For Research Purposes Only

2/26/2002 NB 47/197

Actual Label