Clinical Research Laboratories, Inc.

Final Report

Repeated Insult Patch Test

CLIENT:	**Troy Manufacturing, Inc. 130 Lions Drive Hazleton, Pennsylvania 18201**
ATTENTION:	**Nicholas Pokoluk Director R&D**
TEST MATERIAL:	**Homeopathic Topical Gel FN870, Lot# 12312**
CRL STUDY NUMBER:	**CRL119712**

AUTHORIZED SIGNATURES:

Bruce E. Kanengiser, M.D.
President/Medical Director

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Executive Vice President/COO

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REPORT DATE: **February 21, 2013**

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Good Clinical Practice
Quality Assurance Audit Statement

Clinical Study Number: CRL119712

Start Date: January 7, 2013

Completion Date: February 15, 2013

The clinical study listed above was conducted in accordance with Clinical Research Laboratories, Inc. Standard Operating Procedures, which incorporate the principles of Good Clinical Practice defined by applicable guidelines and regulations established by U.S. Regulatory Agencies. The conduct of the study was monitored for compliance, and the associated records, including source documents or raw data, were reviewed for documentation practices and accuracy by a Project Manager/Study Director and/or a Quality Assurance Representative. Standard Quality Assurance audit procedures for this final report and study related documents were conducted.

Karen Hayhurst
Signature of QA Auditor

Feb. 21, 2013
Date

Clinical Research Laboratories, Inc.

FINAL REPORT

REPEATED INSULT PATCH TEST

PURPOSE

The purpose of this study was to determine the dermal irritation and sensitization potential of a test material.

INVESTIGATIVE SITE

Clinical Research Laboratories, Inc.
371 Hoes Lane, Suite 100
Piscataway, New Jersey 08854
732-981-1616

TEST MATERIAL

The following test material was provided by Troy Manufacturing, Inc. and was received by Clinical Research Laboratories, Inc. on December 19, 2012:

Test Material	Test Condition	Patch Type
Homeopathic Topical Gel FN870, Lot# 12312	Test as Received	Semi-occlusive*

The test material was coded with the following CRL identification number:

CRL119712

STUDY DATES

This study was initiated on January 7, 2013 and was completed on February 15, 2013 .

* Semi-occlusive Strip (Brady Medical, Mesquite,TX)

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PANEL SELECTION

Each subject was assigned a permanent CRL identification number. All subjects signed an Informed Consent Form in compliance with 21 CFR Part 50: "Protection of Human Subjects" and a HIPAA Authorization Form in compliance with 45 CFR Parts 160 and 164. All subjects completed a Subject Profile/Medical History Form provided by Clinical Research Laboratories, Inc. prior to the study (Subject Demographics - Appendix I). Subjects who met the following Inclusion Criteria and none of the Exclusion Criteria were impaneled:

Inclusion Criteria

a. Male and female subjects between the ages of 18 and 70 years;

b. Subjects who do not exhibit any skin diseases which might be confused with a skin reaction from the test material;

c. Subjects who agree to avoid exposure of the test sites to the sun and to refrain from visits to tanning salons during the course of this study;

d. Subjects who agree to refrain from getting patches wet during the course of the study;

e. Subjects willing to sign an Informed Consent in conformance with 21CFR Part 50: "Protection of Human Subjects;"

f. Subjects who have completed a HIPAA Authorization Form in conformance with 45CFR Parts 160 and 164;

g. Subjects in generally good health who have a current Subject Profile/Medical History on file;

h. Subjects who are dependable and able to follow directions as outlined in the protocol.

Exclusion Criteria

a. Female subjects who are pregnant or nursing;

b. Subjects who are currently using any systemic or topical corticosteroids, anti-inflammatory drugs, or antihistamines on a regular basis;

c. Subjects exhibiting any skin disorder, sunburn, scars, excessive tattoos, etc. in the test area.

TEST METHOD

Prior to the application of the patch, the test area was wiped with 70% isopropyl alcohol and allowed to dry. The test material, which was prepared as described in the Test Material section of the report, was applied to the upper back (between the scapulae) and was allowed to remain in direct skin contact for a period of 24 hours.

Patches were applied to the same site on Monday, Wednesday, and Friday for a total of 9 applications during the Induction Period. This schedule may have been modified to allow for missed visits or holidays. If a subject was unable to report on an assigned test date, the test material was applied on 2 consecutive days during the Induction Phase and/or a makeup day was added at the end of the Induction Phase.

The sites were graded by a CRL technician for dermal irritation 24 hours after removal of the patches by the subjects on Tuesday and Thursday and 48 hours after removal of the patches on Saturday, unless the patching schedule was altered as described above.

The sites were graded according to the following scoring system:

Dermal Scoring Scale

0 No visible skin reaction
± Barely perceptible erythema
1+ Mild erythema
2+ Well defined erythema
3+ Severe erythema and edema
4+ Erythema and edema with vesiculation

If a "2+" reaction or greater occurred, the test material was applied to an adjacent virgin site. If a "2+" reaction or greater occurred on the new site, the subject was not patched again during the Induction Phase but was challenged on the appropriate day of the study. At the discretion of the Study Director, patch sites with scores less than a "2+" may have been changed.

Following approximately a 2-week rest period, the challenge patches were applied to previously untreated test sites on the back. After 24 hours, the patches were removed by a CRL technician and the test sites were evaluated for dermal reactions. The test sites were re-evaluated at 48 and 72 hours. Subjects exhibiting reactions during the Challenge Phase of the study may have been asked to return for a 96-hour reading.

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RESULTS

This study was initiated with 56 subjects. Two subjects discontinued study participation for reasons unrelated to the test material. A total of 54 subjects completed the study.

Individual dermal scores recorded during the Induction and Challenge Phases appear in Table I.

CONCLUSION

Based on the test population of 54 subjects and under the conditions of this study, the test material identified as Homeopathic Topical Gel FN870, Lot# 12312 did not demonstrate a potential for eliciting dermal irritation or sensitization.

RETENTION

Test materials and all original forms of this study will be retained by Clinical Research Laboratories, Inc. as specified in CRL Standard Operating Procedures 30.6 and 30.6C, unless designated otherwise by the Sponsor.

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TABLE I

Summary of Dermal Scores

Test Material:	Homeopathic Topical Gel FN870, Lot# 12312

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
57	0	0	0	0	0	0	0	0	0	0	0	0
58	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
60	0	0	0	0	0	0	0	0	0	0	0	0
61	0	0	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0
76	0	0	0	0	0	0	0	0	0	0	0	0
77	0	0	0	0	0	0	0	0	0	0	0	0
78	0	0	0	0	0	0	0	0	0	0	0	0
79	0	0	0	0	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0	0	0	0	0

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TABLE I
(Continued)

Summary of Dermal Scores

Test Material:	Homeopathic Topical Gel FN870, Lot# 12312

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
81	0	0	0	0	0	0	0	0	0	0	0	0
82	0	0	0	0	0	0	0	0	0	0	0	0
83	0	0	0	0	0	0	0	0	0	0	0	0
84	0	0	0	0	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0	0	0	0	0
86	0	0	0	0	0	0	0	0	0	0	0	0
87	0	0	0	0	0	0	0	0	0	0	0	0
88	0	0	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	0	0	0	0
93	0	0	0	0	0	0	0	0	0	0	0	0
94	0	0	0	0	0	0	0	0	0	0	0	0
95	0	0	0	0	0	0	0	0	0	0	0	0
96	0	0	0	0	0	0	0	0	0	0	0	0
97	0	0	0	0	0	0	0	0	0	0	0	0
98	0	0	0	0	0	0	0	0	0	0	0	0
99	0	0	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	Discontinued		
101	0	0	0	0	0	0	0	0	0	0	0	0
102	0	0	0	0	0	0	0	0	0	0	0	0
103	0	0	0	0	0	0	0	0	0	0	0	0
104	0	0	0	0	0	0	0	0	0	0	0	0
105	0	0	0	0	0	0	0	0	0	0	0	0

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TABLE I
(Continued)

Summary of Dermal Scores

Test Material:	Homeopathic Topical Gel FN870, Lot# 12312

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
106	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0
108	0	0	0	0	0	0	0	0	0	0	0	0
109	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	0	0	0	0	0	0	0	0	0	0
111	0	0	0	0	0	0	0	0	0	0	0	0
112	0	0	0	0	0	0	0	0	0	Discontinued		

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Appendix I

Subject Demographics

Subject Number	Subject Initials	CRL ID #	Age	Sex
57	BS	31140	52	F
58	JB	26258	42	F
59	EC	00064	53	F
60	PP	24795	63	F
61	MP	29569	22	F
62	JE	06932	56	F
63	KM	20892	38	F
64	BB	01668	49	F
65	DB	05269	58	F
66	LB	13590	51	F
67	HS	29427	25	F
68	MM	30669	42	F
69	DM	29474	55	F
70	JM	29472	59	M
71	DC	12376	57	F
72	MM	30773	37	F
73	TP	14507	52	F
74	DA	24796	59	F
75	ML	23940	24	F
76	AJ	01976	70	M
77	PE	25599	51	F
78	AG	30249	68	F
79	RK	25864	58	F
80	LN	14920	57	F
81	EB	24168	50	M
82	MF	01488	53	F
83	DF	23673	23	M
84	CF	28371	41	F

Subject Number	Subject Initials	CRL ID #	Age	Sex
85	EJ	17508	63	F
86	NP	27720	53	F
87	MM	29656	25	F
88	OS	29248	32	F
89	EL	26069	51	F
90	AM	22877	46	F
91	DG	16950	54	F
92	MM	20961	52	F
93	PA	27725	53	F
94	SZ	27683	55	F
95	DJ	29662	40	M
96	AC	19727	27	F
97	JG	17522	41	F
98	ME	01693	57	F
99	DL	03280	42	F
100	PT	03483	67	F
101	OC	14123	56	F
102	MS	16397	70	M
103	RA	20421	55	F
104	DK	21563	51	F
105	FK	04033	64	M
106	LB	29209	47	M
107	RR	03677	54	F
108	TT	24709	62	F
109	LG	28238	51	F
110	MB	28939	50	F
111	GM	19186	51	F
112	DT	04398	35	M