Clinical Research Laboratories, Inc.

Report Status:	Final Report
Report Date:	August 4, 2014
CRL Study Number:	CRL47714
CRL Protocol Number:	CL 1.0 2014
Study Dates:	June 18, 2014 - July 25, 2014
Study Title:	Repeated Insult Patch Test (RIPT) –Shelanski Method
Test Material:	FN 875 Gel
Sponsor:	Troy Manufacturing, Inc. 130 Lions Drive Hazleton, Pennsylvania 18201
Sponsor Representative:	Nicholas Pokoluk Director R&D and Quality Assurance
Investigator:	Anita Lee Cham, M.D. Dermatologist

APPROVAL SIGNATURES:

Bruce E. Kanengiser, M.D. — Date: 8/7/14
President/Medical Director

Michael J. Muscatiello, Ph.D. — Date: 8/7/14
Executive Vice President/COO

Anita Lee Cham, M.D. — Date: 8/4/14
Dermatologist

371 Hoes Lane, Suite 100 • Piscataway, NJ 08854 • (732) 981-1616 • FAX (732) 981-0520

Clinical Research Laboratories, Inc.

Good Clinical Practice
Quality Assurance Audit Statement

Clinical Study Number: CRL47714

Start Date: June 18, 2014

Completion Date: July 25, 2014

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.

The Project Manager verifies that the clinical study listed above was executed according to the study protocol and all documentation contained in the study file accurately reflects the conduct of the study.

Signature of Project Manager — Date: August 6, 2014

Signature of QA Auditor — Date: August 4, 2014

Clinical Research Laboratories, Inc.

FINAL REPORT

Repeated Insult Patch Test (RIPT) - Shelanski Method

1.0 OBJECTIVE

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

2.0 INVESTIGATOR/INVESTIGATIVE SITE

Anita Lee Cham, M.D.
Dermatologist

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

3.0 SPONSOR REPRESENTATIVE/SPONSOR

Nicholas Pokoluk
Director R&D and Quality Assurance

Troy Manufacturing, Inc.
130 Lions Drive
Hazleton, Pennsylvania 18201

4.0 TEST MATERIAL

The following test material was provided by Troy Manufacturing, Inc. and was received by Clinical Research Laboratories, Inc. on June 6, 2014.

Test Material	Test Condition	Patch Type
FN 875 Gel	Test as received	Semi-occlusive*

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

CRL47714

5.0 STUDY DATES

This study was initiated on June 18, 2014 and was completed on July 25, 2014.

* Semi-occlusive Strip (Strukmyer LLC, Mesquite,TX or equivalent)

6.0 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:

6.1. INCLUSION CRITERIA

a. Subject is male or female between the ages of 18 and 70 years;

b. Subject does not exhibit any skin diseases which might be confused with a skin reaction from the test material;

c. Subject agrees 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. Subject agrees to refrain from getting patches wet during the course of the study;

e. Subject has signed an Informed Consent in conformance with 21CFR Part 50: "Protection of Human Subjects;"

f. Subject has completed a HIPAA Authorization Form in conformance with 45CFR Parts 160 and 164;

g. Subject is in generally good health and has a current Subject Profile/Medical History on file;

h. Subject is dependable and able to follow directions as outlined in the protocol.

6.2. EXCLUSION CRITERIA

a. Subject is pregnant, nursing, or planning to become pregnant;

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

c. Subject reports allergies to cosmetics, toiletries, or personal care products;

d. Subject exhibits any skin disorders, sunburn, scars, excessive tattoos, etc. in the test area;

e. Subject has scheduled, or is planning to undergo, any medical or surgical procedures during the 6 week course of the study.

7.0 TEST METHOD SUMMARY

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 may not have been patched again during the Induction Phase but may have been 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.

8.0 RESULTS

This study was initiated with 56 subjects. Seven subjects discontinued study participation for reasons unrelated to the test material. A total of 49 subjects completed the study.

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

9.0 ADVERSE EVENTS

No adverse events were reported during the study.

10.0 CONCLUSION

Based on the test population of 49 subjects and under the conditions of this study, the test material identified as FN 875 Gel did not demonstrate a potential for eliciting dermal irritation or sensitization.

11.0 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.

Clinical Research Laboratories, Inc.

TABLE I

Summary of Dermal Scores

Test Material:	FN 875 Gel

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
1	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
3	0	0	0	0	0	0	0	0	0	0	0	0
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
6	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
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	Discontinued								
10	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
12	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
14	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
16	0	0	0	0	0	0	0	0	0	±	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	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
21	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
23	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
25	0	0	0	0	0	0	0	0	0	0	0	0

Clinical Research Laboratories, Inc.

TABLE I
(Continued)

Summary of Dermal Scores

Test Material:	FN 875 Gel

Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
26	0	0	0	0	0	0	0	0	0	0	0	0
27	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
29	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
31	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	X*
33	0	0	0	0	Discontinued							
34	0	0	0	0	0	0	0	0	0	0	0	0
35	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
37	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
39	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
41	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	Discontinued							
43	Discontinued											
44	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
46	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
48	0	0	0	0	0	**---C	±	0	0	0	0	0
49	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

C = Changed Site
X = Subject Absent
*Subject Absent for the 96 hour evaluation
**Subject 48 site changed due to insect bite – Unable to score

Clinical Research Laboratories, Inc.

TABLE I
(Continued)

Summary of Dermal Scores

Test Material:	FN 875 Gel

Subject Number	**Induction Scores**									**Challenge Scores**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**24 Hour**	**48 Hour**	**72 Hour**
51	0	Discontinued										
52	0	0	0	Discontinued								
53	0	0	Discontinued									
54	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
56	0	0	0	0	0	0	0	0	0	0	0	X*

X = Subject Absent
*No reaction was observed at the 96 hour evaluation

Clinical Research Laboratories, Inc.

Appendix I

Subject Demographics

Subject Number	Subject Initials	CRL ID #	Age	Sex
1	MF	32952	42	F
2	PG	13069	64	F
3	SR	32960	31	F
4	LV	31441	23	F
5	PB	32930	56	F
6	BW	06687	66	F
7	BW	26154	61	F
8	AD	32954	46	F
9	AD	32956	25	F
10	AS	32959	44	F
11	AB	20464	45	F
12	EJ	17508	65	F
13	DA	32951	53	F
14	JM	32969	47	M
15	LW	27465	61	F
16	HS	30646	57	F
17	WC	32967	43	F
18	NG	32949	63	M
19	YG	32354	46	F
20	CW	32970	59	F
21	JD	01639	60	F
22	ED	20237	55	F
23	RW	02714	53	F
24	TW	31128	45	M
25	MB	08386	50	F
26	LS	29285	56	F
27	GD	32416	39	F
28	OF	32888	37	M

Subject Number	Subject Initials	CRL ID #	Age	Sex
29	ML	28203	63	F
30	AK	15733	36	F
31	MM	32941	63	F
32	ZH	13977	57	F
33	AL	32958	35	F
34	TH	30703	49	F
35	DG	32931	32	F
36	PT	21754	50	M
37	GB	25248	52	F
38	KP	31622	24	F
39	PM	32945	54	F
40	PE	32051	34	F
41	SB	32944	47	F
42	BC	32973	19	F
43	SW	31672	44	F
44	SK	30063	40	M
45	LP	15115	50	F
46	MW	32948	48	M
47	AP	31912	47	F
48	ST	20592	30	F
49	SP	29581	42	F
50	FM	32947	59	F
51	EF	31224	54	F
52	MV	06227	58	F
53	NM	27767	21	F
54	AS	31453	56	M
55	MR	21928	38	F
56	MR	32529	36	F