



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

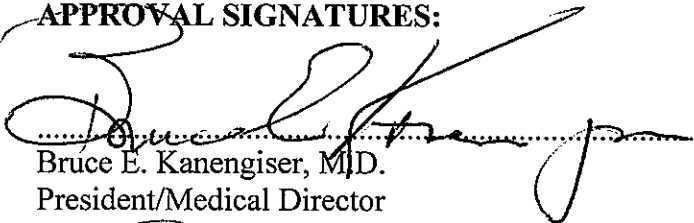
Test Material: FN 875 Gel

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

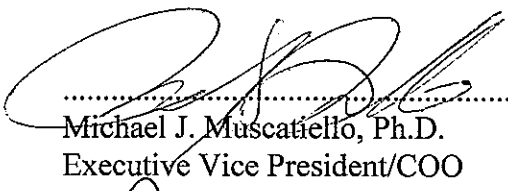
APPROVAL SIGNATURES:



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

8/17/14

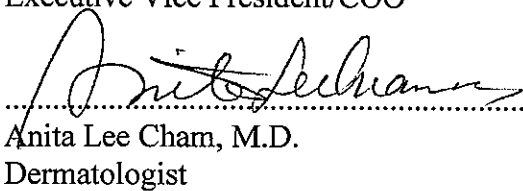
 Date



 Michael J. Muscatiello, Ph.D.
 Executive Vice President/COO

8/4/14

 Date



 Anita Lee Cham, M.D.
 Dermatologist

8/4/14

 Date



Clinical Research Laboratories, Inc.

Good Clinical Practice Quality Assurance Audit Statement


Clinical Study Number: CRL47714

Start Date: June 18, 2014

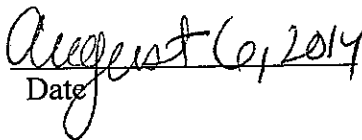
Completion Date: July 25, 2014

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.



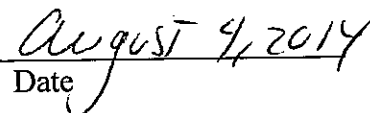
Signature of Project Manager



Date



Signature of QA Auditor



Date



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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)



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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.



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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.



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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.



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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



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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



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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 |