Research Report S06-87

Confidential Material

A Single Blind, Randomized, Controlled Long Term Leg Regression Study with TFA S06-87 in Patients with Moderate to Severe Dry Skin

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Respectfully submitted by:

22 Dec 2006

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22 Dec 2006

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I. OBJECTIVE

The primary objective of this study was to assess the efficacy and duration of therapeutic activity of a test formulation topically applied to dry skin of the legs.

II. EXPERIMENTAL DESIGN

A. General Considerations

This study was conducted under the supervision Gary Grove, Ph.D. and Charles Zerweck, Ph.D., at cyberDERM Clinical Studies in Broomall, Pennsylvania. Copies of Dr. Grove's and Dr. Zerweck's curriculum vitae are on file with the Sponsor.

In conducting this study, we followed current Good Clinical Practices (cGCP) and current Good Laboratory Practices (cGLP) guidelines as well as the COLIPA Efficacy Testing Guidelines.

A calendar of events outlining the schedule of treatments and evaluative procedures that were followed during this study is attached as **Appendix A**.

This was a single-blind, randomized, controlled study. Approximately 15 panelists were selected who had moderate to severe dry skin on the outer calves as determined by an Expert Grader. The selected panelists then discontinued the use of all moisturizing products on their legs for one week prior to the start of the study. At Baseline, all panelists had each outer calf assessed by an Expert Grader. Instrumental measurements of skin surface hydration and water loss were taken of one test site on each outer calf. Following these assessments, the panelists were instructed to apply the test material to either the right or left outer calf according to a randomization schedule. One leg remained non-treated for the study duration to serve as a non-treated control. Except for scheduled visits, the product applications were applied by the panelist at home.

The panelists applied the test product to the designated outer calf twice daily for four weeks. After 1, 2, 3 and 4 weeks of treatment, the assessments taken at Baseline were repeated. The panelists' twice daily treatment of their one leg was discontinued on Day 29 (Week 4), with their last treatment being on Day 28 in the evening. The panelists returned for assessments and measurements after 3, 5 and 8 days of regression (Days 31, 33 and 36).

Pertinent details of panelist selection, product applications, clinical assessments and instrument methods will be provided in the sections that follow.

B. Panelist Selection

Approximately 15 volunteers were recruited for this study from a group of healthy females ages 18-65 who were willing to comply with the requirements of this experimental design. In order to participate in this study, they must have had visual dryness scores on the outer calves of 4 or greater on a 0-8 scale. They were interviewed to ascertain that they had no medical problems, no known allergies to moisturizers, soaps or fragrances, and were not using concomitant medications that might have interfered with the study results. The inclusion/exclusion criteria were as follows:

1. Inclusion Criteria

a. Female panelists between the ages of 18 and 65.
b. Has a visual dryness score of 4 or greater (0-8 scale) on the legs as determined by an Expert Grader.
c. Is willing to refrain from using moisturizers, body lotions, creams, oils or any other topical products on the test sites for the 1 week prior to the study start and for the duration of the study.
d. Agrees to adhere to the shaving restrictions (must shave legs 30 hours prior to all measurements).
e. Agrees not to swim, use a sauna or tanning salon for the duration of study.
f. Agrees not to exercise before each instrumental visit as this will affect the measurements.
g. Is able to read, understand, and sign the consent form.

2. Exclusion Criteria

a. Is pregnant, nursing or planning a pregnancy during the study period.
b. Has a history of any significant skin condition other than dry skin on their legs (i.e. psoriasis, eczema, contact dermatitis, etc), or atopic dermatitis.
c. Has scars, moles or other blemishes on the legs that would obscure grading or measuring of the test sites.
d. Has known allergies to cosmetics, moisturizers, or fragrances. Active symptoms of an allergic reaction of skin, e.g. hives or rash on the body, particularly on the legs.
e. Is currently taking hormone replacement therapy (HRT) medications.
f. Currently uses waxes or depilatories to remove hair from the legs.
g. Water loss values on the upper outer calves >10.0 gms/m^2hr.
h. Any other condition or factor the Investigator or his duly assigned representative believes may affect the skin response or the interpretation of the test results.

All volunteers signed a consent form (**Appendix B**) after being informed as to their obligations and risks that they might encounter as a participant in this study. The selected panelists were advised of the general nature of this study and were instructed not to "tamper" with the sites in any way. Each candidate was instructed to stop the use of all moisturizing products on their legs during a 1 week pre-conditioning period prior to testing. In addition, panelists were required to shave their legs approximately 30 hours prior to their Baseline visit and were not allowed to shave their legs again until after their visit.

During the study, the following restrictions were imposed:

- Panelists may not apply any moisturizing products to test sites for 1 week prior to study start and for the duration of the study.
- Panelists must use their normal cleanser/soap as a lather when shaving their legs.
- Panelists must not have scars, moles or other blemishes on the legs that would obscure measuring of the test sites.
- Panelists must agree not to swim, use a sauna or tanning salon for the duration of study.
- Panelists may not exercise before each instrumental visit as this will affect the measurements.
- Panelists will be required to shave their legs approximately 30 hours prior to each of the following weekly visits: Days 1, 8, 15, 22 & 29. They may not shave their legs again until after their visit is completed.
- During the Regression (Days 29-36) the visits are more frequent and panelists must shave their legs in the evening after completing the visits on Days 29 & 31 and again on Day 34. No other shaving is allowed between Days 29-36 except for optional shaving on Day 33 after the visit is completed.

Prior to testing, all candidates were assessed by Charles Zerweck, Ph.D., for suitability to be included on the panel. Any individuals with scars, moles or other blemishes on the legs that would obscure measuring of the test sites were excluded at that time. Qualified panelists were assigned a panelist number in the order of their admittance to the study panel. Dr. Zerweck logged each panelist in and outlined a 5-centimeter by 5-centimeter site on each outer calf for assessments and measurements.

C. Expert Grader Evaluations

Dr. Zerweck served as the Expert Grader for this study. He assessed the amount of visual dryness, texture and crepiness on each of the test sites which were located on outer calves at the -1 week visit, Baseline and after 1, 2, 3 and 4 weeks of treatment (Days 8, 15, 22 and 29) as well as after 3, 5 and 8 days of regression (Days 31, 33 and 36). The following grading scales were used:

Visual Dryness

Grade	Description
0	None
1-2	Slight flaking/uplifting of flakes (patchy and/or powdered appearance)
3-4	Moderate flaking/uplifting flakes (uniform) and/or slight scaling
5-6	Severe flaking/scaling, uplifting of scales and/or slight fissuring
7-8	Severe scaling/uplifting scales; with severe fissuring/cracking

Texture

Grade	Description
0	Normal, smooth skin
1-2	Slight, but definite roughness
3-4	Moderate roughness
5-6	Marked roughness
7-8	Very marked roughness

Crepiness

Grade	Description
0	Smooth, normal, healthy skin
1-3	Small, circular fine lines, may not be real obvious at first glance; see more with twisting of the skin; less than 25%
4-6	Obvious lined pattern, may look like circular lines/may look "puffy"; more than 25% coverage but to a lesser degree
7-9	Up to 100% coverage of the outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines

The data for each session was manually recorded by the Expert Grader on a worksheet. The Expert Grader was not permitted to review the grades that he had given in any previous session.

D. Instrumental Measurements

All measurements were taken following a 25-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at 68 $\pm$ 2°F.

1. IBS Skicon-200 Conductance Meter

As has been shown, most notably by Obata and Tagami [Obata, M. and Tagami, H. A rapid in vitro test to assess skin moisturizers. In: J. Soc. Cosmet. Chem., 41, 235-241 (July/August, 1990)], the ability of an alternating current to flow through the stratum corneum is an indirect measure of its water content. The value recorded which is expressed in units of micromho (microsiemens) represents the AC conductance 2-3 seconds after placing the spring-loaded probe tip to the sample

site. This timing interval is sufficiently long enough for the electronic circuits to stabilize in response to this change in conductance but short enough not to be influenced by an increased hydration at the probe tip due to its being occlusive and acting as a hindrance to the normal water loss at the test site.

In this study, we employed an IBS Skicon-200 Conductance Meter equipped with a Measurement Technologies probe to further enhance its ability to measure changes in skin surface hydration. It was anticipated that moisturizers would lead to increased conductance values over time.

Mr. Jonn Damia with the assistance of Dr. Zerweck took five conductance measurements from one test site on the right and left outer calves at Baseline (Day 1) prior to treatment. Measurements were taken again after 1, 2, 3 and 4 weeks of treatment (on Days 8, 15, 22 and 29) and after 3, 5 and 8 days of regression (on Days 31, 33 and 36). The average value was computed for each site after each measurement session.

2. Water Loss Measurements – cyberDERM Research Grade Evaporimeter

At Baseline, evaporative water loss measurements were taken from each of the outer calf test sites as described below. Any individuals with water loss values outside the normal range (>10.0 gms/m^2hr) were excluded at this time.

Evaporative water loss measurements provide an instrumental assessment of skin barrier function. These measurements were made using a recently calibrated cyberDERM RG1 Evaporimeter System (Broomall, PA) with TEWL Probes that were manufactured by Cortex Technology (Hadsund, Denmark) and available in the US through cyberDERM, inc. (Broomall, PA).

This instrument is based on the vapor pressure gradient estimation method as designed by Nilsson and initially utilized by the Servo Med Evaporimeter. There are slight dimensional differences and the sensor technology is greatly improved in the DermaLab® TEWL probe but the underlying principles of the measurement remain the same. Both probes contain two sensors that measure the temperature and relative humidity at two fixed points along the axis normal to the skin surface. This arrangement is such that the device can electronically derive a value that corresponds to evaporative water loss expressed in gm/m^2hr. Evaporimetery with TEWL Probe is more fully described in two publications by Grove et al:

Grove, G.L., M.J. Grove, C. Zerweck and E. Pierce: Comparative metrology of the evaporimeter and the DermaLab® TEWL probe. Skin Res. & Tech. 5:1-8, 1999.

Grove, G.L., M.J. Grove, C. Zerweck and E. Pierce: Computerized evaporimetry using the DermaLab® TEWL probe. Skin Res. & Tech. 5:9-13, 1999.

The guidelines established for using the Servo Med Evaporimeter as described by Pinnagoda [Pinnagoda, J., R.A. Tupker, T. Anger and J. Serup. Guidelines for transepidermal water loss (TEWL) measurement. In: Contact Dermatitis 1990: 22:164-178] are quite appropriate for the DermaLab® TEWL Probe as well.

The cyberDERM RG1 Evaporimeter System is completely computerized and continuously communicates with its PC through a USB port and associated cyberDERM, inc. software for the Evaporimeters. We use the application program entitled x1WL2M that captures the water loss data from the attached evaporimeter at a sampling rate of 8 inputs/second. These inputs are graphed as a real time display on the computer monitor. The extracted value refers to the average evaporative water loss rate collected over a twenty-second interval once steady state conditions had been achieved. These are directly transferred to an Excel file using a DDE link.

At each session, duplicate water loss readings were taken from each outer calf site and electronically recorded using a spreadsheet format based on Excel software that computes the average value for each test site. These values were also manually recorded on a worksheet that served as a back up in case there were problems with the computerized records.

Such measures provide a noninvasive method for determining the barrier function of the stratum corneum. Damage leads to a disruption of the barrier that is accompanied by elevated water loss rates.

Measurements were taken by Mr. Damia with the assistance of Dr. Zerweck from the 2 sites located on the outer calves on Baseline (Day 1) prior to treatment. Measurements were also taken of the 2 sites located on the outer calves during the treatment phase on Days 8, 7, 15, 22 and 29 as well as during the regression phase on Days 31, 33 and 36.

E. Treatments and Procedures

1. Test Products

The test material, TFA S06-87 topical formulation, was provided by the Sponsor in individual containers that could be dispensed to each panelist. The panelists were given a new supply of the test product each week during the treatment phase. The test products were kept refrigerated prior to being dispensed each week.

2. Treatment Procedures

The assignment of a patient number and subsequent placement on the randomization chart was in order of appearance on the first day of the treatment phase. The test product was assigned to the right or left outer calf according to the randomization schedule **(Appendix C)**. The other leg remained non-treated for the duration of the study to serve as a control.

After completing the instrument measurements on Day 1, a technician instructed the panelists to apply the product to the designated outer calf at the conclusion of the Baseline visit according to the Sponsor's instructions (**Appendix D**).

The panelists were provided with a diary form to record the times of their applications. The panelists were also provided with an instruction sheet to follow for their treatments at home (**Appendix D**).

The panelists applied test materials to the designated site on the entire outer calf twice daily for 4 weeks. The panelists' last treatment was on Day 28 in the evening. The panelists' test products and diaries were collected on their Day 29 visit.

3. Panelist Compliance and Product Tolerance

Mrs. Carol Cesari monitored each panelist's morning treatment on their outer calf on Days 8 (Week 1), 15 (Week 2) and 22 (Week 3). At these visits, she monitored the panelist treatments to ensure that each panelist was treating properly. Mrs. Cesari also interviewed each panelist to see if they were having any problems tolerating the product and reviewed their product application diary. If a panelist had a problem tolerating the product, it would have been noted on the tolerance/compliance form for that visit and the panelist would have then been referred to Dr. Charles Zerweck for irritation assessments.

The remaining treatments and all evening and weekend applications were performed by the panelist at home.

F. Adverse Reactions

Definition

An adverse event (AE) is any undesirable event occurring to a subject during a clinical trial, whether or not considered related to the trial product. This includes events not seen at baseline.

All AE's are classified as either: Serious Adverse Events (SAE)
Non-Serious Adverse Events (AE)

Serious Adverse Event
A serious adverse event is any experience that suggests a medically significant hazard including any event that:

> is fatal, is life threatening, is permanently disabling, requires in patient hospitalization (requiring overnight admission), prolongs hospitalization, causes a congenital abnormality, is diagnosed as cancer, is an over-dose or under-dose and results in inpatient hospitalization.
>
> Pre-planned elective procedures are not to be reported as serious adverse events.

Reporting of SAE
The investigator/designate must report SAE to the Sponsor within 24 hours of knowledge of the event. The information must be provided by phone or fax to the Sponsor and IRB/Ethics Committee.

Non-Serious Adverse Event
All adverse events not classified as serious will be reported and non-serious adverse events. At each visit all adverse events observed by the investigator/designate or reported by subject spontaneously must be evaluated and recorded on the standard adverse event form. A non-serious adverse event is further classified with respect to severity and relationship to the trial product:

Severity:

Mild:	Transient symptoms, easily tolerated, no interference with subjects daily activities.
Moderate:	Marked symptoms, moderate interference with subjects daily activities and tolerable.
Marked:	Considerable interference with subject's daily activities, not tolerable.
Note:	Pre-planned elective procedures should be reported as non-serious adverse events.

Relationship to trial product:
All serious adverse events and non-serious adverse events must be evaluated by the investigator with respect to its relationship to the trial product as follows:

Probable:	Good reasons and sufficient documentation to assume causal relationship
Possible:	Causal relationship is likely and cannot be excluded.
Unlikely:	The event is most likely related to an etiology other than the trial treatment.

Unknown: Unable to assess due to insufficient evidence, conflicting data or poor documentation.

G. Statistical Analysis

Dr. Grove was responsible for devising a sorting template that is based on Excel 2003 spreadsheet software and implemented on the IBM clone desktop computer. The sorted data for each parameter was tabulated and arranged in order of panelist number for every point of evaluation. In creating these tables, column averages were computed in every case, but only to give a preliminary look at the findings.

Dr. Grove was also responsible for statistical analysis of the findings using the statistics package available in the Excel 2003 environment. To allow the use of parametric statistics, the Expert Grader's ratings which are ordinal data were considered as though they are interval measurements as discussed in some detail in Munro, Visintainer and Page Statistical Methods for Health Care Research, p. 6 (J.B. Lippincott Company, Philadelphia, PA 1986).

For the Expert Grader assessments and instrumental measurements, a Paired T-Test was used to compare the treated and non-treated sites at each point in time. For all analyses, a two tailed $p < 0.05$ was taken as the level of significance.

III. RESULTS

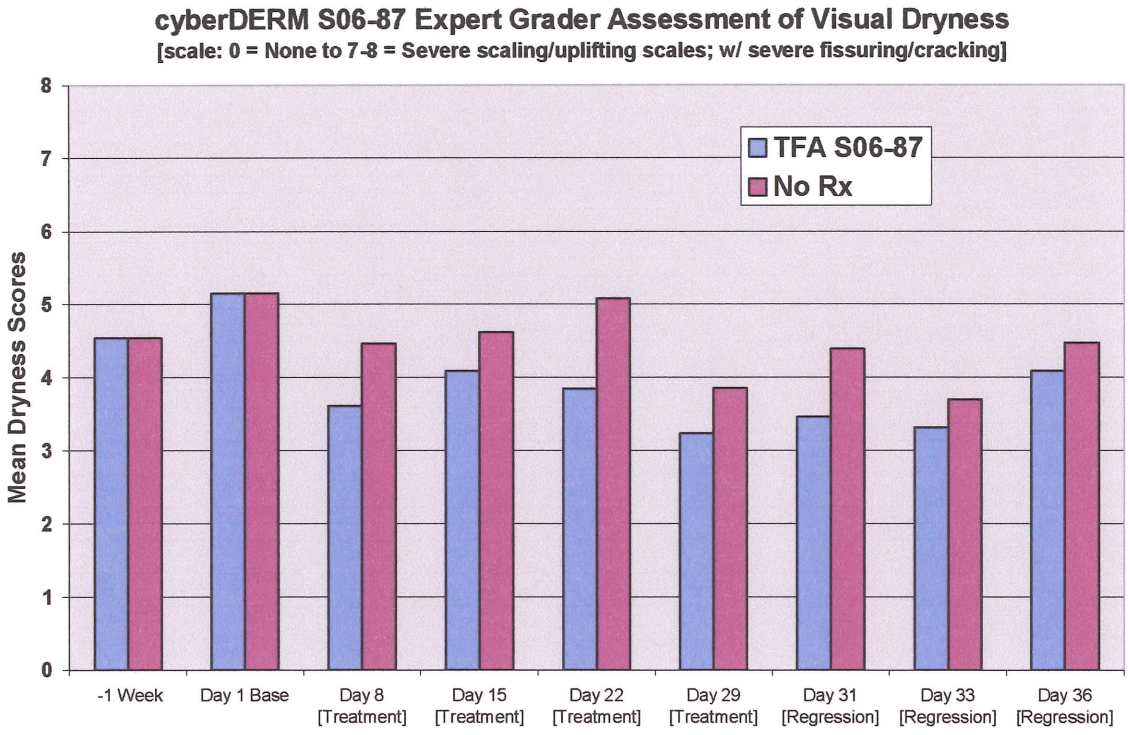
A. Panelist Accountability

Fourteen panelists reported to the test facility for Baseline measurements, all of whom qualified for inclusion on the study panel. **Appendix E** contains a listing of each panelist's age and sex.

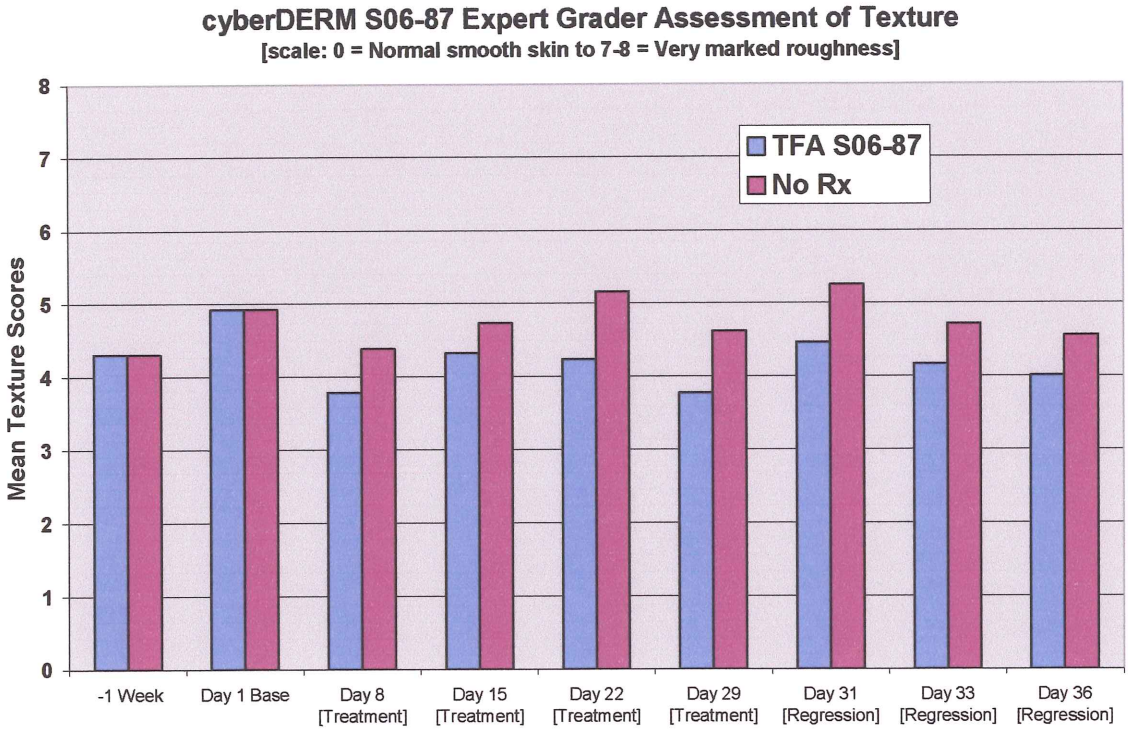
During the study, one panelist (#14 B004) was dropped due to non-compliance. The remaining 13 panelists were able to successfully complete the entire course of the study. We have no reason to believe that the remaining panelists were not fully compliant with all provisions of this study.

B. Expert Grader Evaluations

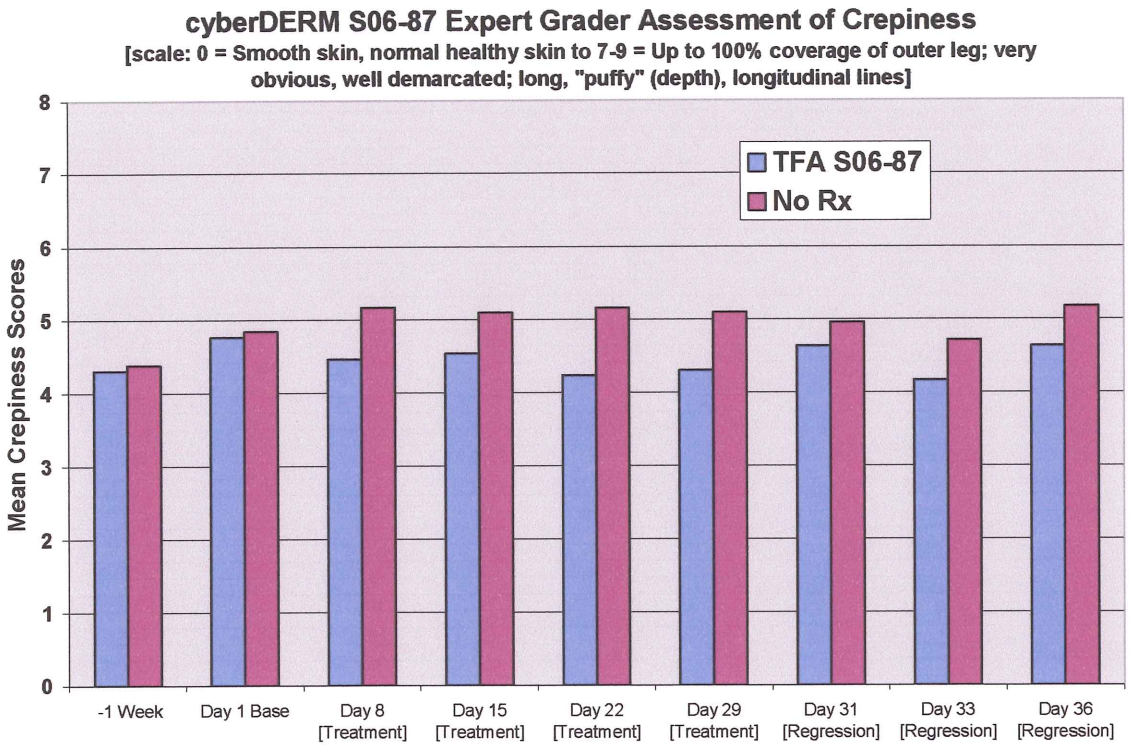
The decoded and sorted Expert Grader dryness, texture and crepiness data from the sessions at the -1 week visit, Baseline and after 1, 2, 3 and 4 weeks of treatment (Days 8, 15, 22 and 29) as well as after 3, 5 and 8 days of regression (Days 31, 33 and 36) are attached as **Appendix F**. These results are also graphically summarized in the figures below:



The results of Expert Grader assessments of visual dryness reveal a rather modest improvement in mean dryness scores compared to no treatment at every time point following the initial seven days of the treatment regimen. This difference is found to be statistically significant ($p < 0.05$) on Days 8 and 22 during the treatment phase as well as on Day 31 (Day 3 of the regression phase).



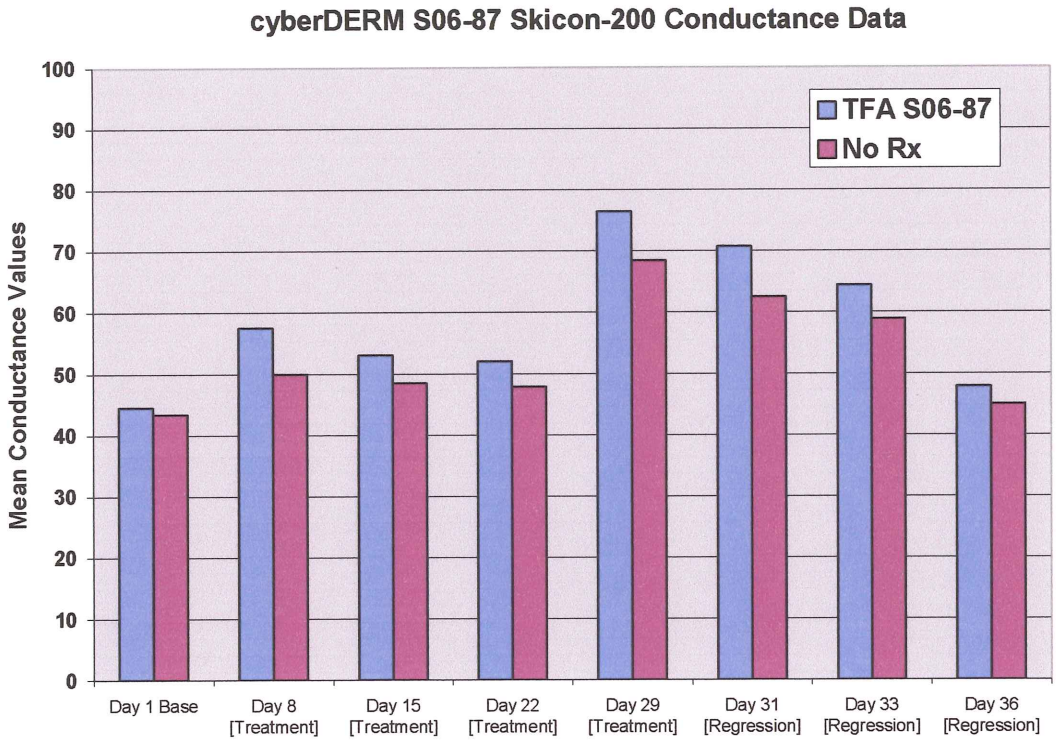
The results of Expert Grader assessments of tactile roughness reveal a modest improvement in mean roughness scores compared to no treatment at every time point following the initial seven days of the treatment regimen. This difference is found to be statistically significant ($p < 0.05$) on Days 22 and 29 during the treatment phase as well as on Days 31 and 36 (Days 3 and 8 of the regression phase).



The results of Expert Grader assessments of visual Crepiness reveal a modest improvement in mean Crepiness scores compared to no treatment at every time point following the initial seven days of the treatment regimen. This difference is found to be statistically significant ($p < 0.05$) on Days 22 and 29 during the treatment phase as well as on Days 33 and 36 (Days 5 and 8 of the regression phase).

C. Skicon-200 Conductance Measurements

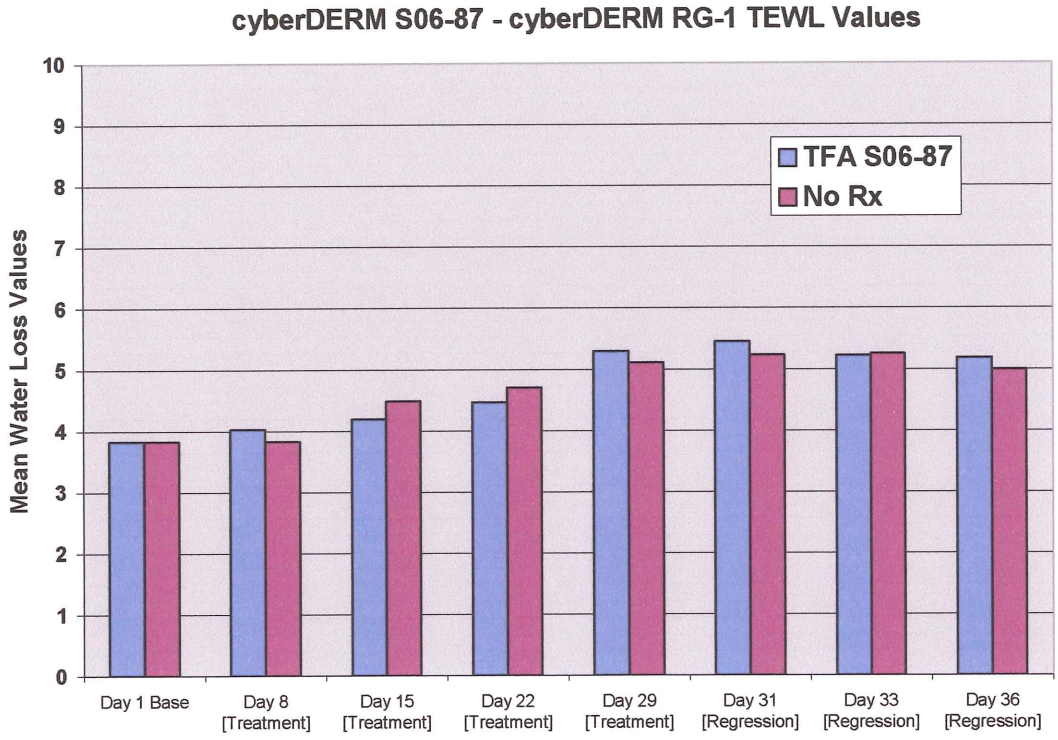
The decoded and sorted conductance measurement data from the sessions at Baseline and after 1, 2, 3 and 4 weeks of treatment (Days 8, 15, 22 and 29) as well as after 3, 5 and 8 days of regression (Days 31, 33 and 36) are attached as **Appendix G**. These results are also graphically summarized in the figure below.



The results of electrical conductance measurements failed to reveal any statistically significant differences between treatment and no treatment groups.

D. Water Loss Measurements – cyberDERM, inc. Evaporimeter

The decoded and sorted water loss measurement data from the sessions at Baseline and after 1, 2, 3 and 4 weeks of treatment (Days 8, 15, 22 and 29) as well as after 3, 5 and 8 days of regression (Days 31, 33 and 36) are attached as **Appendix H**. These results are also graphically summarized in the figure below.



The results of evaporative water loss measurements failed to reveal any statistically significant differences between treatment and no treatment groups.

IV. CONCLUSIONS

Based on the Expert Grader results of this study it is reasonable to conclude that treatment with the test formulation as described, results in discernible though modest improvements in visual dryness and crepiness as well as tactile roughness when applied to skin of dry legs. Results of instrumental assessments of skin hydration and skin barrier function did not reveal any significant improvements with treatment.

V. PROPRIETARY PROTOCOL AND NON-ENDORSEMENT POLICY

This research protocol is considered to be proprietary and confidential by cyberDERM, inc. It is not to be shared with any third party except appropriate government regulatory agencies without written consent of an officer of cyberDERM Clinical Studies or cyberDERM, inc. The name of cyberDERM, inc., cyberDERM Clinical Studies, any officer, employee or collaborating scientist are not to be used for any advertising, promotional or sales purposes without the written consent of cyberDERM, inc. or cyberDERM Clinical Studies. If there are any questions regarding this policy, please contact Dr. Gary Grove.

VI. RECORD RETENTION

Please be advised that the records for this study will remain on file at cyberDERM, inc. (or a remote storage site) for a period of 1 year from the issue date of the final report and then destroyed unless we are notified otherwise by the Sponsor using the form accompanying this final report. It is the duty of the Sponsor to ensure that the completed form is promptly returned to cyberDERM.

Appendix A: Calendar of Events

cyberDERM CLINICAL STUDIES

cyberDERM #S06-87:
LONG TERM LEG REGRESSION STUDY

	Pre-Trial	Treatment Phase					Regression Phase		
	-1 Week	Day 1	Day 8	Day 15	Day 22	Day 29	Day 31	Day 33	Day 36
Expert Grader assessments	X	X	X	X	X	X	X	X	X
cyberDERM RG-1 TEWL measurements		X	X	X	X	X	X	X	X
Skicon-200 Conductance measurements		X	X	X	X	X	X	X	X
One of the twice daily treatments supervised at lab		X	X	X	X	Collect Rx			

CONDUCTION DATES: October 9-November 20, 2006

PRE-TRIAL CONDITIONING:
Panelists will stop the use of all moisturizing products on their legs for the 1 week prior to study start. In addition, panelists will be required to shave approximately 30 hours prior to their Baseline appointment.

PANEL:
Fifteen panelists will be recruited to finish with at least 12 panelists. The panel will consist of females ages 18-65, with moderate to severe dry skin on the legs (visual dryness grade $\geq$4 on a 0-8 scale).

TEST SITES:
The two test sites will be located on the outer calves (1 on each leg). Panelists will treat the entire designated outer calf.

TEST PRODUCTS & TREATMENTS:
The test product will be supplied by the Sponsor with dosage and use instructions. The panelists will treat one entire designated outer calf and the other leg will remain non-treated to serve as a control. A technician will supervise one of the panelist's treatments on Days 1, 8, 15 and 22.

EXPERT GRADER ASSESSMENTS:
An Expert Grader will assess each of the outer calf test sites for visual dryness, texture and crepiness. Assessments will be made at -1 week, Day 1 (Baseline/prior to treatment) and during the Treatment Phase on Days 8, 15, 22 and 29, and also during the Regression Phase on Days 31, 33 and 36 (Regression Days 3, 5 and 8).

cyberDERM
CLINICAL STUDIES

cyberDERM #S06-87:
LONG TERM LEG REGRESSION STUDY (continued)

INSTRUMENTAL MEASUREMENTS:
Panelists will be required to acclimate in an environmentally controlled room for approximately 30 minutes prior to all measurements.

The following measurements will be taken from each test site on Day 1 (Baseline, prior to treatment) and again on Days 8, 15, 22, 29, 31, 33 and 36:

- Transepidermal water loss measurements will be taken from each test site in duplicate with a cyberDERM Research Grade Evaporimeter and the average value will be computed for each site.

- Five conductance measurements will be taken from each test site with an IBS Skicon-200 Conductance Meter and the average value will be computed for each site.

DATA ANALYSIS & REPORT:
For the Expert Grader assessments and instrumental measurements, a Paired T-Test will be used to compare the treated and non-treated sites at each point in time. For all analyses, a two tailed $p < 0.05$ will be taken as the level of significance.

A draft report will be completed by cyberDERM Clinical Studies and forwarded to the Sponsor for review. A final report will be issued after review and approval of the draft report.

PANELIST RESTRICTIONS:

- May not apply any moisturizing products to test sites for 1 week prior to study start and for the duration of the study.
- Must use normal cleanser/soap as a lather when shaving their legs.
- Must not have scars, moles or other blemishes on the legs that would obscure measuring of the test sites.
- Must agree not to swim, use a sauna or tanning salon for the duration of study.
- May not exercise before each instrumental visit as this will affect the measurements.
- Must shave their legs 30 hours before all appointments.

Appendix B: Consent Form

Subject Number: _____ CCS ID:_____

SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Single Blind, Randomized, Controlled Long Term Leg Regression Study with TFA S06-87 in Patients with Moderate to Severe Dry Skin

PROTOCOL NO.: cyberDERM #S06-87, AkPharma #TFA Leg Reg 2006

INVESTIGATOR: Gary L. Grove, Ph.D.
Telephone: 610-325-0112 (Day)
610-358-2381 (Night)

CO-INVESTIGATOR: Charles R. Zerweck, Ph.D.
Telephone: 610-325-0112 (Day)
610-627-9236 (Night)

STUDY SITE: cyberDERM Clinical Studies
700 Parkway Drive
Broomall, Pennsylvania 19008
Telephone: 610-325-0112

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

INTRODUCTION
Before agreeing to enroll in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from this study at any time. No guarantees or assurances can be made as to the results of the study.

This study is being conducted for a consumer product company. cyberDERM Clinical Studies is being paid by the study sponsor to conduct this study.

BACKGROUND AND PURPOSE OF STUDY
This study is designed to determine the ability of the test product to demonstrate an improvement in the condition of moderate to severely dry skin on the legs.

This study is under the direction of Drs. Gary L. Grove and Charles R. Zerweck.

Approximately 15 volunteers will enroll in this study.

LENGTH OF STUDY AND PROCEDURES USED

Your participation in this study will last 43 days and involves 9 study visits. You will be asked to report to the testing facility at specific times during the study. It is important that you report at the designated times. If you agree to participate, the following steps will occur:

Monday, 1 Week prior to testing start:

- An Expert Grader will visually assess your legs to determine if you qualify for the study. If you qualify:
- You will begin a 1 week weaning period. During this time, you must not use moisturizing skin care products (soaps, lotions, aftershave, etc.) on your legs.

On Tuesday through Friday (The 2-5 days prior to testing start):

- Continue wean.

On Saturday (2 days prior to testing start):

- Continue wean. <u>You must shave your legs in the evening today. Do not shave again until after your appointment on Monday.</u>

On Sunday (1 day prior to testing start):

- Continue wean. Do NOT shave your legs today.

Monday, Day 1, start of testing:

- You will have 1 test site (2 inches by 2 inches in size) mapped onto your left and right outer calf (1 on each leg) with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes. During the acclimation and evaluations, your legs must remain exposed to the air.
- You will have the test sites visually graded and instrumentally measured by technicians. Two instruments will be used.
    - One instrument measures Transepidermal Water Loss (referred to as "TEWL" or "TWL"), which is the amount of water evaporating from your skin.
    - Another instrument measures skin surface moisture (referred to as "Skicon or Conductance Meter").
    - With these instruments, a probe is gently placed repeatedly against the skin for a few seconds or up to 1 minute while each non-invasive measurement is taken.
- A technician will instruct you on how to apply the product to either your right or left outer calf. One calf will remain non-treated for the duration of the study to serve as a control. You will receive a diary to record your treatment times and instructions to follow. You will apply the product to the designated calf under the supervision of that technician.
- You will apply the test product at home in the evening to the

designated leg according to the instructions. Record your treatment times on your diary.

- Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Tuesday through Friday, Days 2-5:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary.
- You may shave your legs if desired. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Saturday, Day 6:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary.
- You must shave your legs in the evening today. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.
- Do not shave again until after your appointment on Monday.

Sunday, Day 7:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary.
- You may NOT shave your legs.

Monday, Day 8 (Week 1):

- You will have 1 test site (2 inches by 2 inches in size) mapped onto your left and right outer calf (1 on each leg) with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes. During the acclimation and evaluations, your legs must remain exposed to the air.
- The test site visual grading and instrumental measurements of skin surface moisture and water loss will be repeated.
- You will apply the product to the designated site under the supervision of a technician to ensure that you are treating correctly and are not having any problems tolerating the product.
- You will apply the test product at home in the evening to the designated leg according to the instructions. Record your treatment times

on your diary.

- You may shave your legs if desired after the visit is completed. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Tuesday, Day 9 through Friday, Day 12:

- You will apply the test product at home in the morning and evening according to the instructions.
- You will record your treatment times on your diary.
- You may shave your legs if desired. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Saturday, Day 13:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary.
- <u>You must shave your legs in the evening today.</u> Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.
- <u>Do not shave again until after your appointment on Monday.</u>

Sunday, Day 14:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary.
- You may NOT shave your legs.

Monday, Day 15 (Week 2):

- You will have 1 test site (2 inches by 2 inches in size) mapped onto your left and right outer calf (1 on each leg) with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes. During the acclimation and evaluations, your legs must remain exposed to the air.
- The test site visual grading and instrumental measurements of skin surface moisture and water loss will be repeated.
- You will apply the product to the designated site under the supervision of a technician to ensure that you are treating correctly and are not having any problems tolerating the product.
- You will apply the test product at home in the evening to the designated leg according to the instructions. Record your treatment times on your diary.

- You may shave your legs if desired after the visit is completed. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Tuesday, Day 16 through Friday, Day 19:

- You will apply the test product at home in the morning and evening according to the instructions.
- You will record your treatment times on your diary.
- You may shave your legs if desired. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Saturday, Day 20:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary.
- <u>You must shave your legs in the evening today.</u> Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.
- <u>Do not shave again until after your appointment on Monday.</u>

Sunday, Day 21:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary.
- You may NOT shave your legs.

Monday, Day 22 (Week 3):

- You will have 1 test site (2 inches by 2 inches in size) mapped onto your left and right outer calf (1 on each leg) with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes. During the acclimation and evaluations, your legs must remain exposed to the air.
- The test site visual grading and instrumental measurements of skin surface moisture and water loss will be repeated.
- You will apply the product to the designated site under the supervision of a technician to ensure that you are treating correctly and are not having any problems tolerating the product.
- You will apply the test product at home in the evening to the designated leg according to the instructions. Record your treatment times on your diary.

- You may shave your legs if desired after the visit is completed. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Tuesday, Day 23 through Friday, Day 26:

- You will apply the test product at home in the morning and evening according to the instructions.
- You will record your treatment times on your diary.
- You may shave your legs if desired. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Saturday, Day 27:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary.
- <u>You must shave your legs in the evening today.</u> Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.
- <u>Do not shave again until after your appointment on Monday.</u>

Sunday, Day 28:

- You will apply the test product at home in the morning and evening to the designated leg according to the instructions. You will record your treatment times on your diary. Your last treatment will be this evening.
- You may NOT shave your legs.

Monday, Day 29 (Week 4):

- You will have 1 test site (2 inches by 2 inches in size) mapped onto your left and right outer calf (1 on each leg) with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes. During the acclimation and evaluations, your legs must remain exposed to the air.
- The test site visual grading and instrumental measurements of skin surface moisture and water loss will be repeated.
- Your test product and diaries will be collected.
- Continue to NOT use any moisturizing products on either of your legs. This part of the study is to determine how long lasting the product will be.
- <u>You must shave your legs in the evening today.</u> Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg

second – to avoid potential product cross-over.

- Do not shave again until after your appointment on Wednesday.

Tuesday, Day 30:

- Continue to NOT use any moisturizing products on your legs.
- Do NOT shave your legs today.

Wednesday, Day 31:

- You will have 1 test site (2 inches by 2 inches in size) mapped onto your left and right outer calf (1 on each leg) with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes. During the acclimation and evaluations, your legs must remain exposed to the air.
- The test site visual grading and instrumental measurements of skin surface moisture and water loss will be repeated.
- Continue to NOT use any moisturizing products on your legs.
- You must shave your legs in the evening today. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.
- Do not shave again until after your appointment on Friday.

Thursday, Day 32:

- Continue to NOT use any moisturizing products on your legs.
- Do NOT shave your legs today.

Friday, Day 33:

- You will have 1 test site (2 inches by 2 inches in size) mapped onto your left and right outer calf (1 on each leg) with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes. During the acclimation and evaluations, your legs must remain exposed to the air.
- The test site visual grading and instrumental measurements of skin surface moisture and water loss will be repeated.
- Continue to NOT use any moisturizing products on your legs.
- You may shave your legs if desired. Use your normal cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

Saturday, Day 34:

- Continue to NOT use any moisturizing products on your legs.
- You must shave your legs in the evening today. Use your normal

cleanser/soap as a lather when shaving your legs. Shave both legs in a uniform fashion. Untreated leg should always be shaved first; treated leg second – to avoid potential product cross-over.

- Do not shave again until after your appointment on Monday.

Sunday, Day 35:

- Continue to NOT use any moisturizing products on your legs.
- You may NOT shave your legs.

Monday, Day 36:

- You will have 1 test site (2 inches by 2 inches in size) mapped onto your left and right outer calf (1 on each leg) with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes. During the acclimation and evaluations, your legs must remain exposed to the air.
- The test site visual grading and instrumental measurements of skin surface moisture and water loss will be repeated.
- Your participation in this study will end.

STUDY REQUIREMENTS AND RESTRICTIONS

- Panelists may not apply any moisturizing products to test sites for 1 week prior to study start and for the duration of the study.
- Panelists must use their normal cleanser/soap as a lather when shaving their legs.
- Panelists must not have scars, moles or other blemishes on the legs that would obscure measuring of the test sites.
- Panelists must agree not to swim, use a sauna or tanning salon for the duration of study.
- Panelists may not exercise before each instrumental visit as this will affect the measurements.
- Panelists will be required to shave their legs approximately 30 hours prior to each of the following weekly visits: Days 1, 8, 15, 22 & 29. Untreated leg should be shaved first; treated leg second – to avoid potential product cross-over. They may not shave their legs again after their visit is completed.
- During the Regression (Days 29-36) the visits are more frequent and panelists must shave their legs in the evening after completing the visits on Days 29 & 31 and again on Day 34. Untreated leg should be shaved first; treated leg second – to avoid potential product cross-over. No other shaving is allowed between Days 29-36 except for optional shaving on Day 33 after the visit is completed.

RISKS OR DISCOMFORTS

- The therapy and procedures to be followed in this study may involve the following foreseeable risks and discomforts. You may have possible

lightening or darkening of the skin, skin irritation including, but not limited to, redness, dryness, itching, burning/stinging. This is usually temporary but could persist for a long time (even permanent). Your participation in this study may involve risks that are currently unforeseeable or unknown.

- Your risk may be increased in some situations. You should not participate in this study if you have an active skin infection, psoriasis or active dermatitis. You should also not participate in this study if you are sensitive to cosmetics, toiletries or any other skin care products.

If any of these should occur, the condition of your skin will be closely monitored until it returns to normal. Consultation with a physician will be made, if necessary.

If it is determined that an allergic reaction has occurred, you can expect an allergic reaction to the material if you encounter it at a later date. Whenever possible, you will be told the name of the product that caused the allergic reaction in order that you may avoid contact with it in the future.

You should report any unusual symptoms or signs you may notice during the study, even if you consider such symptoms or signs to be minor or unrelated to the study.

NEW FINDINGS
Significant new findings that develop during the course of this study that may relate to your willingness to continue participation will be provided to you.

BENEFITS TO YOU OR TO OTHERS THAT MAY RESULT FROM THE RESEARCH STUDY
There are no known direct benefits to you as a participant in this investigational study. The findings or results, however, will permit the sponsor to determine the effects of these products.

ALTERNATIVE TREATMENT
As this study is for research purposes only, an alternative would be to not participate in this study.

SUBJECT COMPENSATION
You will be paid $_____ to compensate you for your time and participation if you complete the entire study (-1 Week to Day 36). If you do not complete the study, either by choice (such as not attending a visit) or as instructed by the study investigator for any reason, you will be compensated up to the time of withdrawal at the rate of $_____ per visit. Your payment will be provided after the end of the study.

CONFIDENTIALITY
Records of your participation in this study will be held confidential so far as permitted by law. However, the investigator, the sponsor, and under certain circumstances, the Food and Drug Administration (FDA) will be able to inspect and have access to confidential data which identifies you by name. Any publication of the data will not

identify you. By signing this consent form, you authorize the investigator to release your medical records to the sponsor and the FDA.

COMPENSATION FOR STUDY-RELATED INJURY
In the event that you develop an adverse reaction, side effect, or complication as a result of your participation in this study, emergency medical treatment will be provided by a physician at cyberDERM Clinical Studies at no cost to you. No additional compensation is available. You will not lose any of your legal rights as a research subject by signing this consent form.

EMERGENCY CONTACT
If you have questions about this study, or in the event of a research-related injury or illness, you should call:

Gary L. Grove, Ph.D.		Charles R. Zerweck, Ph.D.
Investigator		Co-Investigator
Telephone:	610-325-0112 (Day)	610-325-0112 (Day)
	610-358-2381 (Night)	610-627-9236 (Night)

Project Coordinator: Danielle Fendrick
Telephone: cyberDERM Clinical Studies - 610-325-0112 (Day)

VOLUNTARY PARTICIPATION/WITHDRAWAL
The investigator can end your participation in this study at any time without your consent for the following reasons: the occurrence of serious side effects, any change in your medical condition that may interfere with the study, pregnancy, failure to attend study visits, failure to follow the treatment regimen or other instructions, or cancellation of the study, or for administrative reasons.

Your participation in this study is entirely voluntary. If you withdraw from the research study, you should notify the technician and/or investigator of your intention to do so and you will be compensated up to the time of withdrawal. You can refuse to participate in the study or quit at any time without loss of any rights or benefits to which you would be entitled. If you quit or are withdrawn from the study, you will be asked to return your unused study materials or have study ending tests and procedures for your safety.

ADDITIONAL COSTS THAT MAY RESULT FROM PARTICIPATION IN THE RESEARCH STUDY
You should incur no costs for participating in this research study. If you fully understand the details and possible risks of this study as outlined above and you still wish to participate, please read the section below carefully. This is important for your protection.

CONSENT

I have read and understand this informed subject consent and hereby consent to take part in the clinical research study. This study may involve some discomfort and there is a potential for adverse experiences. This and my part in the research study have been clearly explained to me, and I have had complete freedom to ask any questions about this study. All of my questions have been answered. I will be given a signed copy of this consent form to keep. I authorize the release of my study-related medical records to the sponsor and the FDA.

Certain products in the study are highly proprietary to the Sponsor. Therefore, I agree to keep confidential the products and all information pertaining thereto. I understand that some individuals with health problems have a higher risk of developing adverse reactions to the test products. I have provided truthful information about my health status to the investigator's staff.

The telephone number listed below is a currently working number I can be reached. If I cannot be reached by telephone, I will be removed from the panel list. I must report to cyberDERM Clinical Studies for study visits as required. IF I DO NOT REPORT OR CALL IN, MY PARTICIPATION IN THIS STUDY MAY BE DISCONTINUED.

I CERTIFY I AM NOT PREGNANT OR NURSING AND DO NOT PLAN A PREGNANCY DURING THIS STUDY. _____(initials)

I HAVE NO CHANGES TO MY MEDICAL HISTORY CARD: _____ (initials)

I CERTIFY THAT I AM NOT CURRENTLY PARTICIPATING IN AND WILL NOT PARTICIPATE IN ANOTHER STUDY ON MY LEGS FOR THE DURATION OF THIS STUDY: _____ (initials)

Please sign both copies of this informed consent and return one to the study investigator. You should keep the other copy.

_____ _____

Printed Name of Volunteer Date

_____ _____

Signature of Volunteer Date

_____ _____ _____ _____

Telephone Number Birth date Age Sex

_____ _____

Person conducting consent discussion Date

Appendix C: Randomization Schedule

cyberDERM CLINICAL STUDIES

cyberDERM #S06-87

Randomized Treatment Map

#	ID	Right	Left
1	C085	Rx	No Rx
2	T014	No Rx	Rx
3	C024	No Rx	Rx
4	B116	No Rx	Rx
5	T005	No Rx	Rx
6	P054	Rx	No Rx
7	S016	Rx	No Rx
8	R001	Rx	No Rx
9	M123	Rx	No Rx
10	C083	No Rx	Rx
11	G004	Rx	No Rx
12	M014	No Rx	Rx
13	G007	No Rx	Rx
14	B004	No Rx	Rx

Appendix D: Treatment Instructions

#: ____ ID: _____ **cyberDERM #S06-87**

You will be treating ONE of your outer calves. The other leg will remain non-treated for the entire study. Do not use any moisturizing products on your legs for the duration of the study.

Apply the product following the instructions below:

Test Product TFA S06-87: APPLY AS INSTRUCTED: Apply two (2) – 1 ½ inch lines onto the assigned outer calf; use one or two fingers to spread over entire assigned treatment area, rubbing treatment into dry skin. Each tube contains approximately six (6) treatment applications.

- Please let your leg air dry before applying clothing to the area.
- Please be sure to complete your diary after every application.
- Wash your hands after completing treatments.
- Avoid product contact with eyes. If product does get into eyes rinse with water.
- **VIP - Do not apply products within 5 hours prior to bathing or shaving so as not to wash off recent applications.**
- Please return all empty test product containers at your next visit. Do NOT throw away empty test product containers.

Requirements and Restrictions:

- Panelists may not apply any moisturizing products to test sites for 1 week prior to study start and for the duration of the study.
- Panelists must use their normal cleanser/soap as a lather when shaving their legs.
- Panelists must not have scars, moles or other blemishes on the legs that would obscure measuring of the test sites.
- Panelists must agree not to swim, use a sauna or tanning salon for the duration of study.
- Panelists may not exercise before each instrumental visit as this will affect the measurements.
- Panelists will be required to shave their legs approximately 30 hours prior to each of the following weekly visits: Days 1, 8, 15, 22 & 29. They may not shave their legs again until after their visit is completed
- During the Regression (Days 29-36) the visits are more frequent and panelists must shave their legs in the evening after completing the visits on Days 29 & 31 and again on Day 34. No other shaving is allowed between Days 29-36 except for optional shaving on Day 33 after the visit is completed.

ON DAYS THAT YOU VISIT cyberDERM CLINICAL STUDIES:

Bring your product and diary with you for **each** visit.

Do not apply the test product prior to evaluations at the center. You will apply the products at the center **after** evaluations are completed.

Appendix E: Demographic Data

cyberDERM #S06-87

Demographic Data

#	ID	AGE	SEX
1	C085	63	F
2	T014	50	F
3	C024	64	F
4	B116	57	F
5	T005	56	F
6	P054	55	F
7	S016	24	F
8	R001	51	F
9	M123	39	F
10	C083	52	F
11	G004	51	F
12	M014	55	F
13	G007	58	F
14	B004	37	F

Appendix F: Expert Grader Assessments

Decoded & Sorted Data **cyberDERM #S06-87**

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
-1 Week / Pre-Trial

#	ID	TFA S06-87	No Rx	
1	C085	5	5	
2	T014	4	4	
3	C024	5	5	
4	B116	4	4	
5	T005	5	5	
6	P054	4	4	
7	S016	4	4	
8	R001	4	4	
9	M123	4	4	
10	C083	5	5	
11	G004	4	4	
12	M014	5	5	
13	G007	6	6	
14	B004			*
	Mean	**4.54**	**4.54**	
	SD	**0.66**	**0.66**	
	paired t-Test	**1.0000**		

* Dropped due to non-compliance

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
Day 1 / Baseline

#	ID	TFA S06-87	No Rx	
1	C085	6	6	
2	T014	4	4	
3	C024	6	6	
4	B116	5	5	
5	T005	5	5	
6	P054	5	5	
7	S016	5	5	
8	R001	5	5	
9	M123	5	5	
10	C083	6	6	
11	G004	4	4	
12	M014	6	6	
13	G007	5	5	
14	B004			*
	Mean	**5.15**	**5.15**	
	SD	**0.69**	**0.69**	
	paired t-Test	**1.0000**		

* Dropped due to non-compliance

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
Day 8 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	5	4	
2	T014	2	4	
3	C024	3	4	
4	B116	3	4	
5	T005	6	5	
6	P054	4	5	
7	S016	2	4	
8	R001	4	6	
9	M123	4	5	
10	C083	4	3	
11	G004	2	4	
12	M014	4	5	
13	G007	4	5	
14	B004			*
	Mean	**3.62**	**4.46**	
	SD	**1.19**	**0.78**	
	paired t-Test	**0.0205**		

* Dropped due to non-compliance

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
Day 15 [Treatment Phase]

#	ID	TFA S06-87	No Rx
1	C085	5	6
2	T014	4	5
3	C024	5	6
4	B116	4.1	4
5	T005	5	5.1
6	P054	4	3
7	S016	4	3
8	R001	4	6
9	M123	5	4
10	C083	2	5
11	G004	4	5
12	M014	2	4
13	G007	5	4
14	B004			*
	Mean	**4.08**	**4.62**
	SD	**1.04**	**1.05**
	paired t-Test	**0.1703**	

* Dropped due to non-compliance

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
Day 22 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	4	6	
2	T014	4	4.1	
3	C024	4	6	
4	B116	3	4	
5	T005	6	5	
6	P054	5	6	
7	S016	4	6	
8	R001	4	6	
9	M123	3	4	
10	C083	3	4	
11	G004	2	5	
12	M014	3	4	
13	G007	5	6	
14	B004			*
	Mean	**3.85**	**5.08**	
	SD	**1.07**	**0.95**	
	paired t-Test	**0.0008**		

* Dropped due to non-compliance

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
Day 29 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	4	4.1	
2	T014	2	4	
3	C024	4	6	
4	B116	1	0	
5	T005	5	6	
6	P054	5	3	
7	S016	4	5	
8	R001	2	4	
9	M123	5	4	
10	C083	2	4	
11	G004	2	3	
12	M014	2	3	
13	G007	4.1	4	
14	B004			*
	Mean	**3.24**	**3.85**	
	SD	**1.43**	**1.52**	
	paired t-Test	**0.1201**		

* Dropped due to non-compliance

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
Day 31 [Day 3 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	4	5	
2	T014	3	4	
3	C024	5	7	
4	B116	2	0	
5	T005	4	5	
6	P054	5	5.1	
7	S016	2	4	
8	R001	3	4	
9	M123	4	5	
10	C083	3	5	
11	G004	4	5	
12	M014	3	4	
13	G007	3	4	
14	B004			*
	Mean	**3.46**	**4.39**	
	SD	**0.97**	**1.56**	
	paired t-Test	**0.0069**		

* Dropped due to non-compliance

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
Day 33 [Day 5 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	R001	2	4	
1	C085	4.1	4	
2	T014	4	3	
3	C024	4	6	
4	B116	2	1	
5	T005	2	3	
6	P054	5	4	
7	S016	4	5	
9	M123	4	4.1	
10	C083	3	5	
11	G004	3	1	
12	M014	2	3	
13	G007	4	5	
14	B004			*
	Mean	**3.32**	**3.70**	
	SD	**1.04**	**1.50**	
	paired t-Test	**0.3162**		

* Dropped due to non-compliance

Expert Grader Assessment
Visual Dryness
[scale: 0 = None to 7-8 = Severe scaling/uplifting scales; w/ severe fissuring/cracking]
Day 36 [Day 8 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	5	5.1	
2	T014	4	4.1	
3	C024	4	6	
4	B116	4	5	
5	T005	6	5	
6	P054	6	5	
7	S016	4	3	
8	R001	4	5	
9	M123	4	5	
10	C083	4	5	
11	G004	2	3	
12	M014	2	3	
13	G007	4.1	4	
14	B004			*
	Mean	**4.08**	**4.48**	
	SD	**1.19**	**0.97**	
	paired t-Test	**0.1658**		

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
-1 Week / Pre-Trial

#	ID	TFA S06-87	No Rx	
1	C085	5	5	
2	T014	3	3	
3	C024	6	6	
4	B116	4	4	
5	T005	6	6	
6	P054	4	4	
7	S016	4	4	
8	R001	3	3	
9	M123	4	4	
10	C083	3	3	
11	G004	4	4	
12	M014	5	5	
13	G007	5	5	
14	B004			*
	Mean	**4.31**	**4.31**	
	SD	**1.03**	**1.03**	
	paired t-Test	**1.0000**		

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
Day 1 / Baseline

#	ID	TFA S06-87	No Rx
1	C085	6	6
2	T014	4	4
3	C024	7	7
4	B116	3	3
5	T005	6	6
6	P054	6	6
7	S016	4	4
8	R001	4	4
9	M123	5	5
10	C083	3	3
11	G004	4	4
12	M014	5	5
13	G007	7	7
14	B004		*
	Mean	**4.92**	**4.92**
	SD	**1.38**	**1.38**
	paired t-Test	**1.0000**	

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
Day 8 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	5	4	
2	T014	3	4	
3	C024	3	4	
4	B116	4.1	4	
5	T005	5.1	5	
6	P054	4	5	
7	S016	2	3	
8	R001	4	7	
9	M123	4	5	
10	C083	2	1	
11	G004	3	5	
12	M014	4	6	
13	G007	6	4	
14	B004			*
	Mean	**3.78**	**4.38**	
	SD	**1.18**	**1.45**	
	paired t-Test	**0.1468**		

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
Day 15 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	3	4	
2	T014	3	4	
3	C024	6	6.1	
4	B116	4	3	
5	T005	5.1	5	
6	P054	4	4.1	
7	S016	4	4.1	
8	R001	4	6	
9	M123	5	5.1	
10	C083	3	3.1	
11	G004	5	6	
12	M014	4	5	
13	G007	6.1	6	
14	B004			*
	Mean	**4.32**	**4.73**	
	SD	**1.05**	**1.10**	
	paired t-Test	**0.0766**		

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
Day 22 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	4	6	
2	T014	4.1	4	
3	C024	6	7	
4	B116	4	3	
5	T005	7	6	
6	P054	5	6	
7	S016	3	4	
8	R001	3	6	
9	M123	3	5	
10	C083	3	3.1	
11	G004	3	5	
12	M014	4	5	
13	G007	6	7	
14	B004			*
	Mean	**4.24**	**5.16**	
	SD	**1.36**	**1.33**	
	paired t-Test	**0.0160**		

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
Day 29 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	3	4	
2	T014	2	4	
3	C024	5	6	
4	B116	3	1	
5	T005	5	6	
6	P054	5	6	
7	S016	4	4.1	
8	R001	3	6	
9	M123	4.1	4	
10	C083	3	4	
11	G004	3	4	
12	M014	4	5	
13	G007	5	6	
14	B004			*
	Mean	**3.78**	**4.62**	
	SD	**1.02**	**1.44**	
	paired t-Test	**0.0206**		

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
Day 31 [Day 3 Regression Phase]

#	ID	TFA S06-87	No Rx
1	C085	5	6
2	T014	4	4.1
3	C024	6	7
4	B116	3.1	3
5	T005	7	7.1
6	P054	6	7
7	S016	3	4
8	R001	3	5
9	M123	6	6.1
10	C083	3	4
11	G004	4	5
12	M014	3	4
13	G007	5	6
14	B004			*
	Mean	**4.47**	**5.25**
	SD	**1.44**	**1.37**
	paired t-Test	**0.0004**	

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
Day 33 [Day 5 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	R001	4	6	
1	C085	4	3	
2	T014	5	4	
3	C024	5	7	
4	B116	3.1	3	
5	T005	4	5	
6	P054	5	5.1	
7	S016	4	6	
9	M123	5	5.1	
10	C083	3	4	
11	G004	3.1	3	
12	M014	4	4.1	
13	G007	5	6	
14	B004			*
	Mean	**4.17**	**4.72**	
	SD	**0.78**	**1.32**	
	paired t-Test	**0.0847**		

* Dropped due to non-compliance

Expert Grader Assessment
Texture
[scale: 0 = Normal smooth skin to 7-8 = Very marked roughness]
Day 36 [Day 8 Regression Phase]

#	ID	TFA S06-87	No Rx
1	C085	4	5
2	T014	4.1	4
3	C024	5	6
4	B116	3.1	3
5	T005	7	6
6	P054	4	5
7	S016	4	4.1
8	R001	4	6
9	M123	4	4.1
10	C083	3	4
11	G004	3	4
12	M014	3	3.1
13	G007	4	5
14	B004		
	Mean	**4.02**	**4.56**
	SD	**1.07**	**1.03**
	paired t-Test	**0.0256**	

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness

[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]

-1 Week / Pre-Trial

#	ID	TFA S06-87	No Rx	
1	C085	6	6	
2	T014	1	2	
3	C024	6	6	
4	B116	7	7	
5	T005	7	7	
6	P054	5	5	
7	S016	1	1	
8	R001	2	2	
9	M123	1	1	
10	C083	3	3	
11	G004	3	3	
12	M014	7	7	
13	G007	7	7	
14	B004			*
	Mean	**4.31**	**4.38**	
	SD	**2.53**	**2.43**	
	paired t-Test	**0.3370**		

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness
[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]
Day 1 / Baseline

#	ID	TFA S06-87	No Rx
1	C085	7	7
2	T014	3	3
3	C024	6	6
4	B116	6	6
5	T005	6	6
6	P054	7	7
7	S016	2	2
8	R001	2	3
9	M123	3	3
10	C083	2	2
11	G004	5	5
12	M014	6	6
13	G007	7	7
14	B004			*
	Mean	**4.77**	**4.85**
	SD	**2.05**	**1.95**
	paired t-Test	**0.3370**	

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness

[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]

Day 8 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	5	5.1	
2	T014	1	2	
3	C024	7	8	
4	B116	5	6	
5	T005	7.1	7	
6	P054	4	6	
7	S016	1	3	
8	R001	1	3	
9	M123	4	5	
10	C083	5	4	
11	G004	3	5	
12	M014	7	7.1	
13	G007	8	6	
14	B004			*
	Mean	**4.47**	**5.17**	
	SD	**2.45**	**1.78**	
	paired t-Test	**0.0658**		

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness

[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]

Day 15 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	5	6	
2	T014	2	4	
3	C024	7	7.1	
4	B116	7	6	
5	T005	5	6	
6	P054	3	4	
7	S016	2	2.1	
8	R001	3	5	
9	M123	3	2	
10	C083	4	6	
11	G004	5	5.1	
12	M014	5	6	
13	G007	8	7	
14	B004			*
	Mean	**4.54**	**5.10**	
	SD	**1.94**	**1.65**	
	paired t-Test	**0.0946**		

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness

[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]

Day 22 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	4	5	
2	T014	3	4	
3	C024	6	6.1	
4	B116	7	6	
5	T005	7.1	7	
6	P054	4	5	
7	S016	2	3	
8	R001	1	3	
9	M123	3	5	
10	C083	2	4	
11	G004	5	6	
12	M014	5	6	
13	G007	6	7	
14	B004			*
	Mean	**4.24**	**5.16**	
	SD	**1.98**	**1.35**	
	paired t-Test	**0.0023**		

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness

[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]

Day 29 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	5	6	
2	T014	1	3	
3	C024	6	7	
4	B116	7	6	
5	T005	6	7	
6	P054	5	5.1	
7	S016	1	3	
8	R001	2	3	
9	M123	4	4.1	
10	C083	4	5	
11	G004	3	3.1	
12	M014	5	6	
13	G007	7	8	
14	B004			*
	Mean	**4.31**	**5.10**	
	SD	**2.06**	**1.74**	
	paired t-Test	**0.0042**		

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness

[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]

Day 31 [Day 3 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	6	5	
2	T014	4.1	4	
3	C024	5	7	
4	B116	5.1	5	
5	T005	7.1	7	
6	P054	6	7	
7	S016	2	2.1	
8	R001	2	2.1	
9	M123	3	3.1	
10	C083	4	4.1	
11	G004	5	5.1	
12	M014	5	6	
13	G007	6	7	
14	B004			*
	Mean	**4.64**	**4.96**	
	SD	**1.57**	**1.81**	
	paired t-Test	**0.1456**		

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness

[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]

Day 33 [Day 5 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	R001	2	4	
1	C085	4.1	4	
2	T014	3	3.1	
3	C024	6	7	
4	B116	5.1	5	
5	T005	6	7	
6	P054	4	5	
7	S016	2	3	
9	M123	2	2.1	
10	C083	4	5	
11	G004	5	4	
12	M014	4	5	
13	G007	7	7.1	
14	B004			*
	Mean	**4.17**	**4.72**	
	SD	**1.63**	**1.59**	
	paired t-Test	**0.0256**		

* Dropped due to non-compliance

Expert Grader Assessment
Crepiness

[scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines]

Day 36 [Day 8 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	6	7	
2	T014	3.1	3	
3	C024	7	8	
4	B116	6.1	6	
5	T005	7.1	7	
6	P054	5	5.1	
7	S016	3	3.1	
8	R001	2	3	
9	M123	2	3	
10	C083	4	5	
11	G004	2	3	
12	M014	6	7	
13	G007	7	7.1	
14	B004			*
	Mean	**4.64**	**5.18**	
	SD	**2.03**	**1.95**	
	paired t-Test	**0.0030**		

* Dropped due to non-compliance

Appendix G: Conductance Data

Decoded & Sorted Data **cyberDERM #S06-87**

Skicon-200 Conductance Meter

Day 1 / Baseline

#	ID	TFA S06-87	No Rx	
1	C085	60.0	55.6	
2	T014	87.2	49.0	
3	C024	33.6	50.0	
4	B116	50.6	56.2	
5	T005	48.6	47.6	
6	P054	29.2	31.2	
7	S016	41.4	44.8	
8	R001	38.6	36.6	
9	M123	39.4	46.0	
10	C083	44.0	49.2	
11	G004	52.4	48.0	
12	M014	31.0	33.2	
13	G007	22.2	16.6	
14	B004			*
	Mean	**44.48**	**43.38**	
	SD	**16.54**	**11.13**	
	paired t-Test	**0.7603**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Day 8 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	67.0	63.2	
2	T014	79.2	50.6	
3	C024	47.0	49.0	
4	B116	64.0	63.8	
5	T005	49.4	47.6	
6	P054	53.0	53.4	
7	S016	47.0	70.6	
8	R001	54.6	29.0	
9	M123	77.0	66.6	
10	C083	53.2	41.2	
11	G004	84.0	65.0	
12	M014	38.0	29.0	
13	G007	33.8	21.0	
14	B004			*
	Mean	**57.48**	**50.00**	
	SD	**15.71**	**16.10**	
	paired t-Test	**0.0688**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Net Change from Baseline @ Day 8 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	7.0	7.6	
2	T014	-8.0	1.6	
3	C024	13.4	-1.0	
4	B116	13.4	7.6	
5	T005	0.8	0.0	
6	P054	23.8	22.2	
7	S016	5.6	25.8	
8	R001	16.0	-7.6	
9	M123	37.6	20.6	
10	C083	9.2	-8.0	
11	G004	31.6	17.0	
12	M014	7.0	-4.2	
13	G007	11.6	4.4	
14	B004			*
	Mean	**13.00**	**6.62**	
	SD	**12.28**	**11.48**	
	paired t-Test	**0.0806**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Day 15 [Treatment Phase]

#	ID	TFA S06-87	No Rx
1	C085	70.0	53.8
2	T014	70.0	39.6
3	C024	38.0	53.6
4	B116	49.4	66.2
5	T005	66.4	65.4
6	P054	44.8	42.6
7	S016	53.8	66.2
8	R001	41.4	33.4
9	M123	66.6	71.8
10	C083	56.6	46.0
11	G004	49.2	37.0
12	M014	52.8	31.4
13	G007	30.8	23.0
14	B004		*
	Mean	**53.06**	**48.46**
	SD	**12.59**	**15.63**
	paired t-Test	**0.2700**	

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Net Change from Baseline @ Day 15 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	10.0	-1.8	
2	T014	-17.2	-9.4	
3	C024	4.4	3.6	
4	B116	-1.2	10.0	
5	T005	17.8	17.8	
6	P054	15.6	11.4	
7	S016	12.4	21.4	
8	R001	2.8	-3.2	
9	M123	27.2	25.8	
10	C083	12.6	-3.2	
11	G004	-3.2	-11.0	
12	M014	21.8	-1.8	
13	G007	8.6	6.4	
14	B004			*
	Mean	**8.58**	**5.08**	
	SD	**11.68**	**11.64**	
	paired t-Test	**0.2254**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Day 22 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	72.2	66.0	
2	T014	56.2	42.6	
3	C024	40.8	47.0	
4	B116	49.2	76.6	
5	T005	42.2	42.8	
6	P054	26.6	30.8	
7	S016	47.4	60.6	
8	R001	73.6	42.6	
9	M123	80.4	53.4	
10	C083	42.8	40.6	
11	G004	53.8	54.8	
12	M014	63.6	50.4	
13	G07	27.0	14.6	
14	B004			*
	Mean	**51.98**	**47.91**	
	SD	**16.94**	**15.64**	
	paired t-Test	**0.3718**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Net Change from Baseline @ Day 22 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	12.2	10.4	
2	T014	-31.0	-6.4	
3	C024	7.2	-3.0	
4	B116	-1.4	20.4	
5	T005	-6.4	-4.8	
6	P054	-2.6	-0.4	
7	S016	6.0	15.8	
8	R001	35.0	6.0	
9	M123	41.0	7.4	
10	C083	-1.2	-8.6	
11	G004	1.4	6.8	
12	M014	32.6	17.2	
13	G07	4.8	-2.0	
14	B004			*
	Mean	**7.51**	**4.52**	
	SD	**19.39**	**9.54**	
	paired t-Test	**0.5412**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Day 29 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	98.2	76.0	
2	T014	78.6	56.2	
3	C024	55.4	53.2	
4	B116	86.4	115.6	
5	T005	70.8	61.0	
6	P054	53.2	81.2	
7	S016	54.8	78.6	
8	R001	88.2	64.8	
9	M123	103.6	90.0	
10	C083	72.2	42.8	
11	G004	101.2	89.0	
12	M014	91.2	61.2	
13	G007	39.8	19.6	
14	B004			*
	Mean	**76.43**	**68.40**	
	SD	**20.67**	**24.12**	
	paired t-Test	**0.2017**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Net Change from Baseline @ Day 29 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	38.2	20.4	
2	T014	-8.6	7.2	
3	C024	21.8	3.2	
4	B116	35.8	59.4	
5	T005	22.2	13.4	
6	P054	24.0	50.0	
7	S016	13.4	33.8	
8	R001	49.6	28.2	
9	M123	64.2	44.0	
10	C083	28.2	-6.4	
11	G004	48.8	41.0	
12	M014	60.2	28.0	
13	G007	17.6	3.0	
14	B004			*
	Mean	**31.95**	**25.02**	
	SD	**20.32**	**20.29**	
	paired t-Test	**0.2606**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Day 31 [Day 3 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	131.6	86.0	
2	T014	59.0	50.8	
3	C024	54.0	58.0	
4	B116	77.4	86.8	
5	T005	55.8	51.4	
6	P054	41.8	34.8	
7	S016	56.4	72.4	
8	R001	80.6	61.4	
9	M123	95.4	92.4	
10	C083	66.4	42.4	
11	G004	84.4	90.4	
12	M014	77.0	59.2	
13	G007	39.6	26.6	
14	B004			*
	Mean	**70.72**	**62.51**	
	SD	**24.75**	**21.73**	
	paired t-Test	**0.0935**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Net Change from Baseline @ Day 31 [Day 3 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	71.6	30.4	
2	T014	-28.2	1.8	
3	C024	20.4	8.0	
4	B116	26.8	30.6	
5	T005	7.2	3.8	
6	P054	12.6	3.6	
7	S016	15.0	27.6	
8	R001	42.0	24.8	
9	M123	56.0	46.4	
10	C083	22.4	-6.8	
11	G004	32.0	42.4	
12	M014	46.0	26.0	
13	G007	17.4	10.0	
14	B004			*
	Mean	**26.25**	**19.12**	
	SD	**24.80**	**16.71**	
	paired t-Test	**0.1930**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Day 33 [Day 5 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	81.2	86.4	
2	T014	69.4	48.4	
3	C024	34.0	38.0	
4	B116	80.2	88.8	
5	T005	66.2	54.2	
6	P054	52.4	39.4	
7	S016	66.6	98.8	
8	R001	49.6	38.4	
9	M123	61.8	68.6	
10	C083	71.6	46.4	
11	G004	101.4	90.4	
12	M014	70.4	45.6	
13	G007	32.4	22.2	
14	B004			*
	Mean	**64.40**	**58.89**	
	SD	**19.02**	**24.80**	
	paired t-Test	**0.2446**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Net Change from Baseline @ Day 33 [Day 5 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	21.2	30.8	
2	T014	-17.8	-0.6	
3	C024	0.4	-12.0	
4	B116	29.6	32.6	
5	T005	17.6	6.6	
6	P054	23.2	8.2	
7	S016	25.2	54.0	
8	R001	11.0	1.8	
9	M123	22.4	22.6	
10	C083	27.6	-2.8	
11	G004	49.0	42.4	
12	M014	39.4	12.4	
13	G007	10.2	5.6	
14	B004			*
	Mean	**19.92**	**15.51**	
	SD	**16.85**	**19.50**	
	paired t-Test	**0.3543**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Day 36 [Day 8 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	79.0	67.4	
2	T014	44.6	34.4	
3	C024	23.8	27.2	
4	B116	48.2	62.0	
5	T005	31.2	38.8	
6	P054	40.6	45.2	
7	S016	36.8	41.0	
8	R001	54.4	41.6	
9	M123	70.8	60.0	
10	C083	42.4	29.6	
11	G004	88.6	78.4	
12	M014	39.2	34.2	
13	G007	22.4	25.2	
14	B004			*
	Mean	**47.85**	**45.00**	
	SD	**20.40**	**16.76**	
	paired t-Test	**0.2859**		

* Dropped due to non-compliance

Skicon-200 Conductance Meter

Net Change from Baseline @ Day 36 [Day 8 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	19.0	11.8	
2	T014	-42.6	-14.6	
3	C024	-9.8	-22.8	
4	B116	-2.4	5.8	
5	T005	-17.4	-8.8	
6	P054	11.4	14.0	
7	S016	-4.6	-3.8	
8	R001	15.8	5.0	
9	M123	31.4	14.0	
10	C083	-1.6	-19.6	
11	G004	36.2	30.4	
12	M014	8.2	1.0	
13	G007	0.2	8.6	
14	B004			*
	Mean	**3.37**	**1.62**	
	SD	**20.82**	**15.18**	
	paired t-Test	**0.6342**		

* Dropped due to non-compliance

Appendix H: Water Loss Data

Decoded & Sorted Data **cyberDERM #S06-87**

cyberDERM RG-1 Evaporimeter
Water Loss Values

Day 1 / Baseline

#	ID	TFA S06-87	No Rx	
1	C085	2.9	2.1	
2	T014	4.4	5.5	
3	C024	2.1	2.8	
4	B116	3.2	3.5	
5	T005	2.7	3.4	
6	P054	4.4	3.6	
7	S016	6.0	4.0	
8	R001	5.8	5.5	
9	M123	3.4	3.1	
10	C083	3.2	4.4	
11	G004	3.7	2.7	
12	M014	4.1	4.8	
13	G007	3.8	4.3	
14	B004			*
	Mean	**3.83**	**3.83**	
	SD	**1.13**	**1.04**	
	paired t-Test	**0.9931**		

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Day 8 [Treatment Phase]

#	ID	TFA S06-87	No Rx
1	C085	3.6	2.7
2	T014	3.2	6.6
3	C024	2.9	2.8
4	B116	2.7	4.5
5	T005	3.8	2.7
6	P054	4.1	1.4
7	S016	5.9	3.3
8	R001	5.8	5.3
9	M123	5.6	3.3
10	C083	3.5	4.4
11	G004	4.1	2.4
12	M014	3.3	4.8
13	G007	3.8	5.6
14	B004		*
	Mean	**4.03**	**3.83**
	SD	**1.08**	**1.50**
	paired t-Test	**0.7166**	

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Net Change from Baseline @
Day 8 [Treatment Phase]

#	ID	TFA S06-87	No Rx
1	C085	0.7	0.6
2	T014	-1.2	1.1
3	C024	0.8	0.0
4	B116	-0.5	1.0
5	T005	1.1	-0.7
6	P054	-0.3	-2.2
7	S016	-0.1	-0.8
8	R001	0.0	-0.2
9	M123	2.2	0.2
10	C083	0.3	0.0
11	G004	0.5	-0.4
12	M014	-0.8	0.0
13	G007	0.0	1.3
14	B004		
	Mean	**0.20**	**0.00**
	SD	**0.89**	**0.93**
	paired t-Test	**0.6000**	

*

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Day 15 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	3.1	3.2	
2	T014	5.2	7.6	
3	C024	2.6	3.9	
4	B116	2.7	4.5	
5	T005	3.6	4.2	
6	P054	5.5	3.9	
7	S016	6.6	4.5	
8	R001	5.5	6.1	
9	M123	4.8	2.8	
10	C083	3.4	5.2	
11	G004	3.0	2.4	
12	M014	3.8	3.9	
13	G007	4.6	6.1	
14	B004			*
	Mean	**4.19**	**4.49**	
	SD	**1.27**	**1.45**	
	paired t-Test	**0.4874**		

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Net Change from Baseline @
Day 15 [Treatment Phase]

#	ID	TFA S06-87	No Rx
1	C085	0.2	1.0
2	T014	0.8	2.1
3	C024	0.5	1.1
4	B116	-0.6	1.0
5	T005	0.8	0.8
6	P054	1.1	0.4
7	S016	0.6	0.5
8	R001	-0.3	0.6
9	M123	1.4	-0.3
10	C083	0.2	0.8
11	G004	-0.7	-0.3
12	M014	-0.3	-0.8
13	G007	0.8	1.8
14	B004		*
	Mean	**0.36**	**0.65**
	SD	**0.65**	**0.81**
	paired t-Test	**0.2698**	

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Day 22 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	3.6	3.8	
2	T014	5.7	9.0	
3	C024	3.3	3.9	
4	B116	4.0	3.7	
5	T005	4.0	4.3	
6	P054	4.3	3.6	
7	S016	5.3	4.1	
8	R001	5.3	5.5	
9	M123	5.0	3.7	
10	C083	3.8	7.6	
11	G004	3.3	1.7	
12	M014	5.0	4.3	
13	G007	5.8	6.1	
14	B004			*
	Mean	**4.47**	**4.70**	
	SD	**0.91**	**1.92**	
	paired t-Test	**0.6169**		

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Net Change from Baseline @
Day 22 [Treatment Phase]

#	ID	TFA S06-87	No Rx	
1	C085	0.7	1.6	
2	T014	1.3	3.5	
3	C024	1.2	1.1	
4	B116	0.7	0.2	
5	T005	1.2	0.9	
6	P054	-0.1	0.1	
7	S016	-0.7	0.0	
8	R001	-0.5	0.0	
9	M123	1.6	0.6	
10	C083	0.5	3.2	
11	G004	-0.4	-1.1	
12	M014	0.9	-0.5	
13	G007	2.0	1.8	
14	B004			*
	Mean	**0.64**	**0.87**	
	SD	**0.86**	**1.37**	
	paired t-Test	**0.4985**		

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Day 29 [Treatment Phase]

#	ID	TFA S06-87	No Rx
1	C085	4.7	3.4
2	T014	6.1	9.9
3	C024	3.0	4.3
4	B116	5.0	4.2
5	T005	4.4	4.5
6	P054	4.5	4.4
7	S016	5.7	3.5
8	R001	5.6	5.6
9	M123	12.6	7.9
10	C083	4.2	5.1
11	G004	3.7	3.3
12	M014	4.9	4.3
13	G007	4.6	6.1
14	B004		*
	Mean	**5.30**	**5.11**
	SD	**2.35**	**1.91**
	paired t-Test	**0.7466**	

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Net Change from Baseline @
Day 29 [Treatment Phase]

#	ID	TFA S06-87	No Rx
1	C085	1.8	1.3
2	T014	1.6	4.4
3	C024	0.9	1.5
4	B116	1.7	0.7
5	T005	1.7	1.1
6	P054	0.0	0.8
7	S016	-0.3	-0.5
8	R001	-0.2	0.1
9	M123	9.3	4.8
10	C083	0.9	0.7
11	G004	0.0	0.6
12	M014	0.9	-0.5
13	G007	0.7	1.8
14	B004		
	Mean	**1.47**	**1.28**
	SD	**2.46**	**1.63**
	paired t-Test	**0.6902**	

*

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Day 31 [Day 3 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	4.3	3.3	
2	T014	6.2	7.4	
3	C024	3.7	5.1	
4	B116	5.2	3.0	
5	T005	4.1	5.3	
6	P054	6.3	4.3	
7	S016	5.8	4.7	
8	R001	6.2	9.2	
9	M123	10.4	7.0	
10	C083	4.2	6.2	
11	G004	5.0	2.9	
12	M014	4.5	3.5	
13	G007	5.1	6.2	
14	B004			*
	Mean	**5.45**	**5.24**	
	SD	**1.74**	**1.91**	
	paired t-Test	**0.7105**		

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Net Change from Baseline @
Day 31 [Day 3 Regression Phase]

#	ID	TFA S06-87	No Rx
1	C085	1.3	1.2
2	T014	1.7	1.9
3	C024	1.6	2.3
4	B116	2.0	-0.5
5	T005	1.3	1.9
6	P054	1.9	0.7
7	S016	-0.2	0.6
8	R001	0.4	3.7
9	M123	7.1	3.9
10	C083	0.9	1.8
11	G004	1.3	0.1
12	M014	0.4	-1.2
13	G007	1.3	1.9
14	B004		*
	Mean	**1.62**	**1.41**
	SD	**1.76**	**1.50**
	paired t-Test	**0.6610**	

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Day 33 [Day 5 Regression Phase]

#	ID	TFA S06-87	No Rx
1	C085	4.3	4.7
2	T014	6.3	5.5
3	C024	4.4	6.2
4	B116	4.6	4.5
5	T005	4.7	4.9
6	P054	4.6	5.4
7	S016	5.5	3.9
8	R001	6.3	7.2
9	M123	5.8	3.6
10	C083	4.0	5.7
11	G004	5.9	4.6
12	M014	5.6	5.1
13	G007	5.9	6.9
14	B004		*
	Mean	**5.22**	**5.25**
	SD	**0.81**	**1.06**
	paired t-Test	**0.9275**	

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Net Change from Baseline @
Day 33 [Day 5 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	1.3	2.6	
2	T014	1.9	0.0	
3	C024	2.3	3.3	
4	B116	1.4	1.0	
5	T005	1.9	1.5	
6	P054	0.2	1.8	
7	S016	-0.5	-0.2	
8	R001	0.5	1.7	
9	M123	2.5	0.6	
10	C083	0.8	1.4	
11	G004	2.3	1.9	
12	M014	1.5	0.3	
13	G007	2.1	2.6	
14	B004			*
	Mean	**1.39**	**1.42**	
	SD	**0.91**	**1.06**	
	paired t-Test	**0.9287**		

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Day 36 [Day 8 Regression Phase]

#	ID	TFA S06-87	No Rx
1	C085	3.8	3.8
2	T014	5.2	7.0
3	C024	3.9	4.3
4	B116	5.1	4.2
5	T005	5.1	4.2
6	P054	5.1	4.8
7	S016	5.5	4.7
8	R001	5.9	7.3
9	M123	8.0	5.8
10	C083	4.5	4.8
11	G004	4.1	3.2
12	M014	4.9	4.8
13	G007	6.5	6.0
14	B004		*
	Mean	**5.19**	**4.99**
	SD	**1.14**	**1.21**
	paired t-Test	**0.5138**	

* Dropped due to non-compliance

cyberDERM RG-1 Evaporimeter
Water Loss Values

Net Change from Baseline @
Day 36 [Day 8 Regression Phase]

#	ID	TFA S06-87	No Rx	
1	C085	0.9	1.7	
2	T014	0.8	1.5	
3	C024	1.8	1.5	
4	B116	1.8	0.7	
5	T005	2.3	0.8	
6	P054	0.7	1.2	
7	S016	-0.5	0.6	
8	R001	0.1	1.8	
9	M123	4.6	2.7	
10	C083	1.3	0.5	
11	G004	0.4	0.5	
12	M014	0.9	0.0	
13	G007	2.6	1.7	
14	B004			*
	Mean	**1.36**	**1.16**	
	SD	**1.32**	**0.73**	
	paired t-Test	**0.5324**		

* Dropped due to non-compliance