SKIN STUDY CENTER

505 PARKWAY, BROOMALL, PA 19008-4204 USA
TELEPHONE: 610-544-8872 FAX 610-544-6305
E-MAIL: kglssc@bellatlantic.net
WEBSITE: www.kgl-inc.com

Final Report

to

AkPharma, Inc.

on

Leg Regression Study

KGL #5305B

January 20, 2004

Submitted by:

James J. Leyden, M.D. — *Date* 1/20/04

Gary L. Grove, Ph.D. — *Date* 20 JAN 2004

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Quality Assurance Officer:

Patricia F. Alfano — *Date* 20 Jan 2004

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I. OBJECTIVE

To evaluate the efficacy of a test product formulation containing Calcium Glycerophosphate as a dermal treatment that will result in an "improved" skin condition with a more youthful "health quality" that is both self-perceived and third-party confirmable.

II. EXPERIMENTAL DESIGN

A. General Considerations

Prior to initiation of the study, the proposed protocol, the informed consent form and the product information was submitted to St. David's Human Research Review Board which was charged with reviewing and approving the study. This study was approved by the to St. David's Human Research Review Board on October 23, 2003. This notification of the Board's approval along with a description by profession of the Board's composition has been provided to the Sponsor prior to the initiation of the study.

This study was conducted under the supervision of James Leyden, M.D. and Gary Grove, Ph.D., at the Skin Study Center in Broomall, Pennsylvania. A copy of Dr. Leyden and Dr. Grove's curriculum vitae are on file with the Sponsor.

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

This study was conducted from October 27, 2003 to December 22, 2003. A calendar of events outlining the schedule of treatments and evaluative procedures followed during this study is attached as ***Appendix A****. The daily weather records covering this time as extracted from newspaper reports were recorded and are attached as* ***Appendix B****. A more detailed account issued by the US Weather Bureau can be provided upon the Sponsor's request.*

Briefly, 20 panelists were selected that had moderately severe dry skin. The panelists discontinued the use of all moisturizing products to their legs for one week prior to their Baseline visit. At Baseline, an Expert Grader assessed dryness, texture, crepiness and overall photoaging for each of the leg test sites (1 site on the lateral aspects of the right and left leg calves). In addition, assessments were taken of each of the leg test sites for each panelist using an IBS Skicon-200 Conductance Meter to measure skin surface hydration and a DermaLab® Modular System with Dual TEWL probes to measure skin surface water loss. After completing the Baseline assessments, panelists were given 1 product to use twice daily on either the right or left leg (1 leg served as a non-treated control) for 4 weeks. After 1, 2, 3 and 4 weeks of treatment, the same assessments/measurements taken at Baseline were repeated.

After the Week 4 (Day 29) assessments were completed, the panelists were instructed to discontinue the treatments, and return on Days 31, 33 and 36 for additional measurements and assessments. They were not to use any other moisturizers on their legs during that 7 day period. Panelists returned on Days 43 and 50 for additional self-assessments.

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

B. Panelist Selection

All volunteers were recruited from a pool of healthy suburban women who meet the inclusion/exclusion criteria attached as ***Appendix C****. Briefly, they were within the range from 45 to 65 years of age and were previously diagnosed with compromised epidermal cell renewal and moderately severe dry skin. Panelists were interviewed to ascertain that they had no medical problems, had no known allergies to soaps or fragrances and were not using concomitant medications that might interfere with the study results. Women who were either pregnant or breast-feeding were also excluded from participating in this study.*

All volunteers signed consent forms after being informed their obligations and risks that they might encounter as a participant in this study. A copy of the consent form used is attached as ***Appendix D****.*

Each candidate was required to discontinue the use of all skin care products on their legs for one week. After this period of "weaning" from whatever skin care products they previously used, the suitability of each individual for acceptance into the final panel was judged by Charles Zerweck, Ph.D., who served as the Expert Grader. Qualified panelists were given a panelist number in order of their acceptance onto the panel.

Upon being selected into the study, the panelists were reminded of the general nature and purpose of this test and instructed not to apply any products nor tamper with their legs in any way during the remaining study period. In addition, the panelists were instructed not to bathe or shower on the follow-up measurement days prior to their appointment at the test facility. The panelists were also not allowed to shave their legs during the 30 hours preceding any measurements.

C. Test Products and Treatments

The test product (Topical Calcium Glycerophosphate) was provided by the Sponsor in individual bottles and labeled with the subject #.

Product application to either the right or left leg followed the randomization schedule attached as ***Appendix E****. The product was dispensed in individual bottles. Product was applied according to the Sponsor's instructions which are attached as* ***Appendix F****.*

The panelists washed and partly dried (leaving the skin a little moist) the areas on their designated leg (lateral aspect of the right or left calves). They mixed the bottle by shaking it several times up and down. The panelists applied 2 or 3 dabs (about the size of peas) of the cream directly onto the test site or onto their fingertips and gently rubbed the cream into the test site. After rubbing in the cream, the panelists wet their fingertips and shook off the excess water and rubbed their fingertips over the treatment site and let the site air dry or they could dab it dry with a towel. A technician monitored each panelist's treatment Days 8, 15, 22 and 29.

The panelists were provided with a diary form to record the time of their twice daily applications. A sample of this diary form is attached as ***Appendix G****.*

D. Expert Grader Assessments

At -1 Week visit and at Baseline as well as after 7, 14, 21 and 18 days of treatment and after 2, 4 and 7 days of regression (Days 31, 33 and 36), Dr. Zerweck, who served as the Expert Grader, assessed dryness, texture, crepiness and overall photoaging using the following scales:

	Dryness		***Texture***
0	*None*	*0*	*Normal, smooth skin*
1-2	*Slight flaking or occasional small lifting scales may be present*	*1-2*	*Slight, but definite roughness*
3-4	*Moderate flaking/scaling*	*3-4*	*Moderate roughness*
5-6	*Marked scaling, slight fissuring, heavy cracking and lifting scales*	*5-6*	*Marked roughness*
7-8	*Severe scaling, fissuring, cracking*	*7-8*	*Very marked roughness*

	Crepiness		***Overall Photoaging***
0	*Smooth, normal, healthy skin*	*0*	*None*
1-3	*Small, circular fine lines, may not be real obvious at first glance; see more with twisting of the skin; less than 25%*	*1-3*	*Mild*
4-6	*Obvious lined pattern, may look like circular lines/may look "puffy"; more than 25% coverage but to a lesser degree*	*4-6*	*Moderate*
7-9	*Up to 100% coverage of the outer leg; very obvious, well demarcated; long, "puffy" (depth), longitudinal lines*	*7-9*	*Severe*

Except at –1Week and at Baseline, the Expert Grader was forced to break any tie scores between test sites by adding 0.1 to the score(s) given to the tied site(s) thought to be worse.

All scores were recorded on the Expert Grader's worksheet, a sample of which is attached as ***Appendix H****.*

E. Self-Assessments

At the -1 Week visit and at Baseline and during the treatment period (Days 1, 8, 15, 22 and 29), and regression period (Days 31, 33 and 36), the panelists were asked to evaluate their legs for dryness, roughness, tightness, itching and burning/sting using the questionnaire attached as ***Appendix I****. The panelists also completed this questionnaire on Days 43 and 50, which were 1 and 2 weeks respectively after the official regression period had ended.*

F. Instrument Evaluations

All instrument evaluations were taken following a 15-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at 70 ± 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 millimho represents the AC conductance 5 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 is anticipated that moisturizers will lead to increased conductance values over time.

Five conductance measurements were taken Mrs. Nancy Bates with the assistance of Mrs. Barbara Quinn from each site at Baseline (prior to treatment) and after 7, 14, 21 and 28 days of twice daily treatments as well as after 2, 4 and 7 days of regression. The average value was computed for each site after each measurement session.

2. Cortex Technology DermaLab® TEWL Meter

Evaporative water loss measurements provide an instrumental assessment of skin barrier function. These measurements were made using recently calibrated DermaLab® Modular Systems with TEWL Probes which were manufactured by Cortex Technology of Denmark and available in the US through cyberDERM, inc. in Media, 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 which 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^{2}hr. The DermaLab® Modular System with TEWL Probe is more fully described in:

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 data from the DermaLab® Modular System is completely computerized and continuously communicates with its PC through a serial port using an RS-232C cable and associated cyberDERM, inc. software for the Evaporimeters. We used the application program entitled C_BASIX_ which captures the water loss data from the attached evaporimeter at a sampling rate of 5 inputs/second. These inputs were 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 were directly transferred to an Excel spread sheet file using a DDE link.

At each session, duplicate water loss readings were taken from each test site by Ms. Elizabeth Pierce and electronically recorded using a spreadsheet format based on Excel 7.0 software which computed the average value for each test site. These values were also manually recorded on a worksheet that serves 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 which leads to elevated water loss rates which directly corresponds to the extent of damage.

G. Statistical Evaluations

Dr. Grove was responsible for devising a sorting template that based on Excel 7.0 spreadsheet software and implemented on the IBM clone desktop computer. The sorted data 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 appropriate GB-STAT software program and the statistics package provided within the Excel 7.0 environment. Descriptive statistics were run on each data set and compared to the preliminary averages to insure that all imported files were correct. A Paired T-Test was used to compare the treatment to its respective non-treated control.

To simplify cross-comparisons and allow the use of more parametric statistics, the Expert Grader's ratings and self-assessments 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). Thus, a Paired T-Test was employed to compare the treatment sites to the non-treated control sites at each point in time.

The approach used by Dr. Grove to analyze the instrument data followed the general recommendations set forth by the International Federation of Society of Cosmetic Chemists in their Monograph on Principles of Product Evaluation: Objective Sensory Methods. In this approach, a Paired T-Test was also employed to compare the treatment sites to the non-treated control sites at each point in time.

III. RESULTS

A. Panelist Accountability

A total of 20 panelists were recruited for this study, 17 of whom completed the entire study. Three panelists (#2 G227, #8 J004 and #16 F010) withdrew for personal reasons unrelated to the study. We have no reason to believe that the remaining panelists were not fully compliant with all provisions of this study. ***Appendix J*** *contains a listing of each panelist's age and sex.*

It should be noted that on Day 33 (Regression Day 4), because of snow conditions, some panelists were unable to make it to the test facility for their assessments. As a result, some individuals have missing data for some of their instruments and Expert Grader evaluations on that day. The means, standard deviations and p values have been eliminated from the data tables and summary tables on Day 33 for this reason. Since this was within the allowable timeframe between Day 31 and Day 36, it does not adversely affect the interpretation of the results.

B. Organization of Results Appendices

The study results have been organized and are attached as appendices. Each of the individual data tables contain the following information:

Actual recorded values
Means & Standard Deviations
Results of Paired T-Tests

C. Expert Grader Data

1. Dryness Scores

A complete set of the Expert Grader dryness data obtained at -1 Week and at Baseline and on Days 8, 15, 22 and 29 and after 2, 4 and 7 days of regression (Days 31, 33 and 36) is attached as ***Appendix K****. Below is a summary of the findings of the Expert Grader data. At no point in time were there any significance differences observed between expert grader's assessments of dryness on the legs treated the topical Calcium Glycerophosphate formulation and the contralateral, non-treated control legs.*

Expert Grader Assessment Dryness (Scale: 0 = None to 7-8 = Severe scaling, fissuring, cracking)							
	No Rx			Rx			p
	Mean	±	Std Dev	Mean	±	Std Dev	
Day -7	5.11	±	1.13	5.11	±	1.13	1.0000
Day 1	5.00	±	0.91	5.00	±	0.91	1.0000
Day 8	5.23	±	0.94	5.08	±	0.87	0.4864
Day 15	4.74	±	1.22	4.90	±	1.13	0.4379
Day 22	4.68	±	0.98	5.00	±	0.97	0.2562
Day 29 (End Rx)	4.73	±	1.03	4.91	±	0.67	0.5206
Day 31 (R2)	5.15	±	1.08	5.18	±	0.92	0.8738
Day 36 (R7)	5.31	±	0.86	4.91	±	0.98	0.1165

2. Texture Scores

A complete set of the Expert Grader texture data obtained at -1 Week and at Baseline and on Days 8, 15, 22 and 29 and after 2, 4 and 7 days of regression (Days 31, 33 and 36) is attached as ***Appendix L****. Below is a summary of the findings of the Expert Grader data. At no point in time were there any significance differences observed between expert grader's assessments of texture of the legs treated the topical Calcium Glycerophosphate formulation and the contralateral, non-treated control legs.*

Expert Grader Assessment Texture (Scale: 0 = Normal, smooth skin to 7-8 = Very marked roughness)							
	No Rx			***Rx***			***p***
	Mean	***±***	***Std Dev***	*Mean*	***±***	***Std Dev***	
Day -7	*5.28*	±	*1.02*	*5.28*	±	*1.02*	*1.0000*
Day 1	*5.00*	±	*1.03*	*5.00*	±	*1.03*	*1.0000*
Day 8	*5.15*	±	*0.94*	*5.07*	±	*1.12*	*0.6326*
Day 15	*5.01*	±	*1.45*	*5.19*	±	*1.42*	*0.3963*
Day 22	*5.09*	±	*1.36*	*5.02*	±	*1.24*	*0.6866*
Day 29 (End Rx)	*4.97*	±	*1.11*	*5.29*	±	*0.84*	*0.1793*
Day 31 (R2)	*5.63*	±	*1.05*	*5.64*	±	*1.04*	*0.9463*
Day 36 (R7)	*5.32*	±	*1.00*	*5.37*	±	*1.21*	*0.7996*

3. Crepiness Scores

A complete set of the Expert Grader crepiness data obtained at -1 Week and at Baseline and on Days 8, 15, 22 and 29 and after 2, 4 and 7 days of regression (Days 31, 33 and 36) is attached as ***Appendix M****. Below is a summary of the findings of the Expert Grader data. At no point in time were there any significance differences observed between expert grader's assessments of crepiness on the legs treated the topical Calcium Glycerophosphate formulation and the contralateral, non-treated control legs.*

Expert Grader Assessment Crepiness ***(Scale: 0 = Smooth, normal, healthy skin to 7-9 = Up to 100% coverage of the outer leg; very obvious, well demarcated; long "puffy" [depth], longitudinal lines)***							
	No Rx			***Rx***			***p***
	Mean	***±***	***Std Dev***	*Mean*	***±***	***Std Dev***	
Day -7	*5.33*	±	*1.37*	*5.33*	±	*1.37*	*1.0000*
Day 1	*5.67*	±	*1.37*	*5.67*	±	*1.37*	*1.0000*
Day 8	*5.99*	±	*1.31*	*6.01*	±	*1.23*	*0.9142*
Day 15	*5.69*	±	*1.38*	*5.87*	±	*1.30*	*0.2563*
Day 22	*5.76*	±	*1.45*	*5.92*	±	*1.32*	*0.2092*
Day 29 (End Rx)	*5.91*	±	*1.54*	*6.20*	±	*1.24*	*0.0778*
Day 31 (R2)	*5.88*	±	*1.39*	*5.98*	±	*1.39*	*0.2307*
Day 36 (R7)	*5.69*	±	*1.28*	*5.74*	±	*1.44*	*0.7351*

4. Overall Photodamage Scores

A complete set of the Expert Grader overall photodamage data obtained at -1 Week and at Baseline and on Days 8, 15, 22 and 29 and after 2, 4 and 7 days of regression (Days 31, 33 and 36) is attached as ***Appendix N****. Below is a summary of the findings of the Expert Grader data. At no point in time were there any significance differences observed between expert grader's assessments of overall photodamage on the legs treated the topical Calcium Glycerophosphate formulation and the contralateral, non-treated control legs.*

Expert Grader Assessment Overall Photodamage (Scale: 0 = None to 7-9 = Severe)							
	No Rx			Rx			p
	Mean	±	Std Dev	Mean	±	Std Dev	
Day -7	5.28	±	1.41	5.28	±	1.41	1.0000
Day 1	5.28	±	1.41	5.28	±	1.41	1.0000
Day 8	5.56	±	1.42	5.51	±	1.15	0.7315
Day 15	5.36	±	1.23	5.64	±	1.21	0.0909
Day 22	5.52	±	1.35	5.66	±	1.23	0.3464
Day 29 (End Rx)	5.63	±	1.43	5.88	±	1.20	0.0740
Day 31 (R2)	5.77	±	1.33	5.82	±	1.30	0.4210
Day 36 (R7)	5.63	±	1.28	5.57	±	1.34	0.5881

D. Self-Assessment Data

A complete set of the self-assessment data obtained –1 Week and at Baseline and on Days 1, 8, 15, 22, 29, 31, 33, 36, 43 and 50 is attached as ***Appendix O****. Below is a summary of the findings. At no point in time were there any significant differences expressed by the panelists in their self-assessments of the legs treated the topical Calcium Glycerophosphate formulation and the contralateral, non-treated control legs.*

Self-Assessment Dryness (Scale: 0 = None to 3 = Severe)							
	No Rx			Rx			p
	Mean	±	Std Dev	Mean	±	Std Dev	
Day -7	2.15	±	0.65	2.10	±	0.66	0.6260
Day 1	2.00	±	0.73	2.08	±	0.55	0.5071
Day 8	2.04	±	0.61	2.01	±	0.78	0.8399
Day 15	1.76	±	0.67	1.68	±	0.60	0.6326
Day 22	1.87	±	0.52	1.57	±	0.86	0.1395
Day 29 (End Rx)	1.79	±	0.81	1.75	±	0.67	0.8402
Day 31 (R2)	1.88	±	0.80	1.84	±	0.80	0.8399
Day 36 (R7)	1.87	±	0.72	1.83	±	0.96	0.8140
Day 43	2.03	±	0.70	1.86	±	0.72	0.3175
Day 50	1.75	±	0.76	1.75	±	0.76	1.0000

Self-Assessment Roughness (Scale: 0 = None to 3 = Severe)							
	No Rx			Rx			p
	Mean	±	Std Dev	Mean	±	Std Dev	
Day -7	1.66	±	0.82	1.74	±	0.90	0.6130
Day 1	1.72	±	0.83	1.76	±	0.77	0.7050
Day 8	1.97	±	0.63	1.85	±	0.80	0.5041
Day 15	1.53	±	0.77	1.24	±	0.66	0.0778
Day 22	1.63	±	0.70	1.40	±	0.92	0.2368
Day 29 (End Rx)	1.79	±	0.81	1.52	±	0.79	0.2739
Day 31 (R2)	1.70	±	0.84	1.68	±	0.85	0.9039
Day 36 (R7)	1.69	±	0.68	1.65	±	0.87	0.8140
Day 43	1.65	±	0.76	1.63	±	0.87	0.8929
Day 50	1.64	±	0.84	1.64	±	0.86	1.0000

Self-Assessment Itching (Scale: 0 = None to 3 = Severe)							
	No Rx			Rx			p
	Mean	±	Std Dev	Mean	±	Std Dev	
Day -7	0.77	±	0.76	0.81	±	0.72	0.7741
Day 1	0.38	±	0.59	0.26	±	0.56	0.1384
Day 8	0.06	±	0.05	0.04	±	0.05	0.3605
Day 15	0.11	±	0.23	0.04	±	0.05	0.3230
Day 22	0.18	±	0.46	0.03	±	0.05	0.1940
Day 29 (End Rx)	0.27	±	0.41	0.27	±	0.55	1.0000
Day 31 (R2)	0.28	±	0.53	0.19	±	0.51	0.4970
Day 36 (R7)	0.36	±	0.59	0.32	±	0.68	0.6473
Day 43	0.29	±	0.74	0.26	±	0.73	0.1631
Day 50	0.17	±	0.31	0.26	±	0.55	0.2889

Self-Assessment Burning/Stinging (Scale: 0 = None to 3 = Severe)							
	No Rx			Rx			p
	Mean	±	Std Dev	Mean	±	Std Dev	
Day -7	0.07	±	0.05	0.03	±	0.05	0.1631
Day 1	0.06	±	0.05	0.04	±	0.05	0.3605
Day 8	0.06	±	0.05	0.15	±	0.46	0.4208
Day 15	0.05	±	0.05	0.10	±	0.23	0.4210
Day 22	0.13	±	0.22	0.08	±	0.26	0.0135
Day 29 (End Rx)	0.12	±	0.22	0.14	±	0.33	0.7903
Day 31 (R2)	0.12	±	0.22	0.14	±	0.47	0.7903
Day 36 (R7)	0.13	±	0.23	0.14	±	0.48	0.8592
Day 43	0.12	±	0.22	0.09	±	0.26	0.1631
Day 50	0.11	±	0.23	0.10	±	0.25	0.6507

E. IBS Skicon-200 Conductance Meter Data

A complete set of the conductance data obtained with the IBS Skicon-200 Conductance Meter at Baseline and Days 8, 15, 22 and 29 and 2, 4 and 7 days of regression (Days 31, 33 and 36) is attached as ***Appendix P****. Below is a summary of the findings. In general, conductance readings were lower on the legs treated the topical Calcium Glycerophosphate formulation compared to the contralateral, non-treated control legs. Indeed, the Day 15 findings demonstrate significant differences in this regard. This means that the current formulation is not moisturizing and in some cases could be drying to the skin. This drying effect was not unexpected since this initial CGP test product formulation was not intended to act like a moisturizer.*

IBS Skicon-200 Conductance Meter (Measurement Technologies Probe)							
	No Rx			***Rx***			***p***
	Mean	***±***	***Std Dev***	***Mean***	***±***	***Std Dev***	
Day 1	83.29	±	29.51	83.97	±	30.42	0.7557
Day 8	71.07	±	21.05	71.17	±	28.47	0.9828
Day 15	107.74	±	35.30	91.73	±	38.60	0.0046
Day 22	103.98	±	32.15	92.74	±	33.83	0.1587
Day 29 (End Rx)	94.77	±	37.43	81.72	±	28.76	0.1736
Day 31 (R2)	74.19	±	20.55	70.46	±	21.16	0.4769
Day 36 (R7)	81.54	±	31.07	70.52	±	21.17	0.0940

F. DermaLab® Water Loss Data

A complete set of the DermaLab® Water Loss data obtained at Baseline and on Days 8, 15, 22 and 29 and 2, 4 and 7 days of regression (Days 31, 33 and 36) is attached as ***Appendix Q****. Below is a summary of the findings. At each point of comparison TEWL was found to be significantly greater in the legs treated the topical Calcium Glycerophosphate formulation compared to their contralateral, non-treated control. This suggests that either: 1) this formulation may be irritating since elevated TEWL rates are an indication that the skin's barrier has been disrupted, or 2) since the patient self-assessments and the expert grader assessments indicated the product to be non-irritating, elevated TEWL rates may be attributed to the drying effect caused by the test product calcium supersaturation.*

DermaLab Water Loss Probe							
	No Rx			Rx			p
	Mean	±	Std Dev	Mean	±	Std Dev	
Day 1	4.79	±	1.15	4.96	±	1.13	0.3337
Day 8	4.97	±	1.11	5.81	±	1.26	0.0003
Day 15	5.57	±	1.54	6.95	±	1.50	<0.0001
Day 22	5.72	±	1.31	6.90	±	1.54	0.0006
Day 29 (End Rx)	5.48	±	1.40	7.18	±	1.47	<0.0001
Day 31 (R2)	6.28	±	1.46	8.20	±	1.91	<0.0001
Day 36 (R7)	7.12	±	1.93	8.40	±	1.89	0.0005

IV. CONCLUSIONS

1. Calf's healthy and youthful appearance:

On the basis of the data collected during the course of this study, it is clear that treating the legs of individuals with moderately severe dryness with this topical formulation of Calcium Glycerophosphate did not significantly improve the condition of the skin cosmetically by causing it to appear more healthy and youthful. This is true whether the comparisons were based on the Expert Grader's observations or the panelist's self-assessments.

2. Skin Hydration and/or Moisturization:

Instrumental measurements of skin surface hydration levels based on AC conductance obtained with the Skicon-200 did not demonstrate that this formulation was an effective moisturizer but rather suggested that it might be actually drying to the skin. However, this drying effect was not unexpected, see F. above, as this test product formulation was not intended to be a moisturizer.

3. Skin Irritation

Data Set I demonstrates that CGP did not act as a topical irritant. An irritant would be expected to exacerbate the deterioration in texture and magnify the observation of "crepiness", but neither the Expert Graders nor the study participants reported either of these effects.

V. RECORD RETENTION

Please be advised that the records for this study will remain on file at KGL, 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 report.

Appendix A

Calendar of Events

CALENDAR OF EVENTS
TOPICAL CALCIUM GLYCEROPHOSPHATE STUDY

	Oct 27	Nov. 3	Nov. 10	Nov. 17	Nov. 24	Nov. 25	Nov. 26	Nov. 28	Dec. 1	Dec. 3	Dec. 5	Dec. 8	Dec. 10	Dec. 12	Dec. 15	Dec. 17	Dec. 19	Dec. 22
DAY:	-1 wk	1	8	15	22	23	24	26	29	31	33	36	38	40	43	45	47	50
		Mon	Mon	Mon	Mon	Tu	Wed	Fri	Mon	Wed	Fri	Mon	Wed	Fri	Mon	Wed	Fri	Mon
Legs – Regression Day:									R0	R2	R4	R7						
Consent	X																	
Screening	X																	
Inc/Exclusions	X	X																
Self	X	X	X	X	X				X	X	X	X			X			X
Grade – Legs	X	X	X	X	X				X	X	X	X						
Skicon – Legs		X	X	X	X				X	X	X	X						
TEWL – Legs		X	X	X	X				X	X	X	X						
Start Rx – Legs		X																
Stop Rx – Legs									X									
Tolerance/Compliance			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Appendix B

Weather Information

2003 WEATHER INFORMATION

MONTH	DATE	DAY	HIGH TEMP °F	LOW TEMP °F	NOON TEMP °F	NOON HUMIDITY %	PRECIP. INCHES
OCTOBER	**27**	**MON**	65	52	64	96	1.35
	28	**TUE**	58	42	56	54	0.19
	29	**WED**	57	50	57	86	0.96
	30	**THU**	63	41	58	45	
	31	**FRI**	72	44	68	56	
NOVEMBER	**1**	**SAT**	78	48	71	62	
	2	**SUN**	74	53	70	70	
	3	**MON**	79	53	73	65	0.01
	4	**TUE**	72	58	66	86	0.01
	5	**WED**	66	58	63	100	0.24
	6	**THU**	64	57	61	89	0.22
	7	**FRI**	59	51	55	56	TRACE
	8	**SAT**	59	51	55	56	TRACE
	9	**SUN**	44	29	43	32	
	10	**MON**	47	28	44	29	
	11	**TUE**	56	34	54	43	TRACE
	12	**WED**	58	48	56	86	0.42
	13	**THU**	61	42	48	35	0.01
	14	**FRI**	48	37	45	36	
	15	**SAT**	54	43	51	45	
	16	**SUN**	55	38	52	58	TRACE
	17	**MON**	60	46	55	83	0.01
	18	**TUE**	57	42	53	89	
	19	**WED**	69	57	67	86	0.44
	20	**THU**	55	48	53	50	0.13
	21	**FRI**	67	40	60	53	
	22	**SAT**	62	42	60	64	
	23	**SUN**	61	42	56	77	
	24	**MON**	66	42	61	75	
	25	**TUE**	45	34	43	45	0.01
	26	**WED**	47	32	45	60	
	27	**THU**	55	38	53	46	

2003 WEATHER INFORMATION

MONTH	DATE	DAY	HIGH TEMP °F	LOW TEMP °F	NOON TEMP °F	NOON HUMIDITY %	PRECIP. INCHES
NOVEMBER	**28**	**FRI**	65	48	59	96	0.44
	29	**SAT**	45	37	44	45	TRACE
	30	**SUN**	51	37	48	42	
DECEMBER	**1**	**MON**	53	39	52	32	
	2	**TUE**	40	30	39	31	TRACE
	3	**WED**	35	21	33	34	
	4	**THU**	40	24	37	45	
	5	**FRI**	36	29	33	95	0.48
	6	**SAT**	30	26	29	85	0.10
	7	**SUN**	31	24	30	59	
	8	**MON**	34	21	32	53	
	9	**TUE**	38	25	35	58	
	10	**WED**	52	30	42	78	0.15
	11	**THU**	60	41	55	77	1.36
	12	**FRI**	42	33	40	48	
	13	**SAT**	35	27	33	43	
	14	**SUN**	44	29	33	95	0.88
	15	**MON**	42	32	41	50	TRACE
	16	**TUE**	48	28	41	57	
	17	**WED**	50	34	50	100	0.54
	18	**THU**	38	31	36	46	
	19	**FRI**	36	27	35	51	TRACE
	20	**SAT**	39	26	38	52	
	21	**SUN**	40	24	34	47	
	22	**MON**	51	33	47	40	

Appendix C

Inclusion/Exclusion Criteria

INCLUSION/EXCLUSION CHECKLIST

#_____ CODE _____ NAME _____ KGL#5305

INCLUSIONS (Answer must be "yes"):		
YES	***NO***	
		1. Informed Consent obtained.
		2. Female, 45-65 years of age previously diagnosed with compromised epidermal cell renewal and moderately severe dry skin
		3. Ambulatory: defined as not depending exclusively on a wheelchair for mobility
		4. Able to remain on stable doses of concomitant medications from the Screening Visit (V1) through the Final Visit (V18) of the study
EXCLUSIONS (Answer must be "no"):		
YES	***NO***	
		1. Pregnant or breast-feeding.
		2. Major psychiatric disorder within the past two years not controlled by a stable dose of medication for the last 6 months.
		3. Alcohol or substance abuse within the past two years.
		4. Participation in any clinical trial within the past 3 months.
		5. Known allergy or hypersensitivity to calcium supplements.

_____ _____

Interviewer ***Date***

Appendix D

Sample Consent Form

INFORMED CONSENT FORM

TITLE: A SINGLE-BLIND, RANDOMIZED, CONTROLLED STUDY WITH TOPICAL CALCIUM GLYCEROPHOSPHATE IN PATIENTS WITH COMPROMISED EPIDERMAL CELL RENEWAL AND MODERATELY SEVERE DRY SKIN

SPONSOR: AkPharma, Inc

PRINCIPAL INVESTIGATOR: James J. Leyden, M.D.
KGL Laboratories - Skin Study Center
505 Parkway
Broomall, PA 19008
610-544-1715
After hours: Dr. Grove: 610-358-2381
Dr. Leyden: 610-251-9775

INTRODUCTION

You are being invited to participate in this research study of a non-prescription skin treatment at KGL Laboratories - Skin Study Center. This study is sponsored by AkPharma Inc. You are being invited to take part because you have moderately severe dry skin with compromised epidermal cell renewal. The active ingredient of this non-prescription skin treatment is calcium glycerophosphate. (CGP)

The purpose of this study is to evaluate if this non-prescription skin treatment reduces your symptoms associated with moderately severe dry skin with compromised epidermal cell renewal. Non-invasive measurements of the skin, expert assessments, logs and questionnaires will be used to determine this.

You will be one of approximately 20 females age 45 – 65 involved in this research project at KGL Laboratories, Skin Study Center. Your participation will last for approximately 8 weeks and will require 19 office visits.

HOW THE STUDY WORKS

VISIT ONE

If you agree to participate in the study and sign this consent form, a member of the study staff will assess your medical history.

You cannot participate in this study if any of the following apply to you:

- Pregnant or breast feeding.
- Major psychiatric disorder within the past two years not controlled by a stable dose of medication

for the last 6 months.

- Alcohol or substance abuse within the past two years.
- Participation in any clinical trial within the past 3 months.
- Known allergy or hypersensitivity to calcium supplements.
- Known allergy or hypersensitivity to dansyl chloride

An expert skin grader will assess the condition of your skin. You will also complete a questionnaire to determine how you feel about your skin condition. We will ask you what medication(s), both prescription and over-the-counter, you are now taking. If there are any changes in your medications, or you become pregnant, during the study, you are to tell us immediately. Your study doctor will determine your continuing status in the study.

If the doctor determines you are an appropriate candidate for the study, you will be required to discontinue the use of all "skin care" products on any parts of your body (face is exempt) through study completion.

VISIT TWO

After a one week "weaning" period from whatever skin care products you previously used, you will return for an office visit, at which your suitability for continuation in the study will be determined by Charles Zerweck, Ph.D.

If you continue in the study, you will be "randomized" into one of two treatment groups:

(1)Topical CGP applied twice daily to the LEFT arm and leg as instructed – OR -
(2) Topical CGP applied twice daily to the RIGHT arm and leg as instructed.

Being randomized means that you are put into a group by a chance process, like flipping a coin. Your chance of being assigned to either treatment group is equal. Please do not disclose this information. The doctors who assess your skin condition throughout the study won't know which group you are in, until the study is over.

You will be provided with application instructions. You will be instructed to apply the study product to the appropriate (LEFT or RIGHT) arm and leg according to the instructions provided.

You will be instructed not to apply any products, other than those provided, nor to tamper with your arms and legs in any way during the remaining study period. You will be instructed to allow the study product to be absorbed by the skin before covering again with any clothing. You will be instructed not to bathe or shower on the day of your study visits until after your evaluations have been completed by the Skin Study Center. You will be instructed to not shave your legs within 30 hours prior to each evaluative study visit.

You will be asked to complete a self-assessment questionnaire about your skin condition with the help of a study staff member. You will also be asked about any changes in medication or any problems you may have experienced since the last visit. An expert skin grader will assess the condition of your skin and non-

invasive measurements of the leg test sites will be taken.

You will be given a one week supply of study treatment. You will also be given a "Patient's Application Log" to record the time of your twice daily applications to be completed and returned at your next visit.

VISITS THREE & FOUR

You will return to the office for Visit Three one week after Visit Two; then one week after Visit Three for Visit Four. At Visit Three and at Visit Four you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert skin grader will assess the condition of your skin and non-invasive measurements of the leg test sites will be taken. You will bring your completed "Patient's Application Log" to these visits along with your remaining study treatment. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

VISITS FIVE, SIX & SEVEN

You will return to the office for Visit Five one week after Visit Four. You will bring your completed "Patient's Application Log" to these visits along with your remaining study treatment. At Visit Five treatment to the arm test sites will be temporarily suspended. The arm test sites will be stained using a suspension of 5% Dansyl Chloride in white petrolatum and covered with a dressing. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

Visit Six will be six hours after Visit Five. At Visit 6, a second application of the dye will be made and the dressings renewed.

Visit Seven will be scheduled ~~two~~ one days after Visit Six. At Visit Seven, the dressings will be removed and the test sites will be thoroughly washed with soap and water. After being patted dry, each arm test site will be examined under a Wood's lamp and the acceptability of staining determined by Dr. Charles Zerweck. If Dr. Zerweck determines that the UV staining is not acceptable then the dansyl patches will be reapplied and you will be required to return to the office six hours later that day for acceptability. Study product application will resume on the evening the dressings are removed and will continue twice daily thereafter.

VISITS EIGHT & NINE

You will return to the office for Visit Eight one day after Visit Seven, then again two days after Visit Eight for Visit Nine. At these visits you will inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your remaining study treatment.

VISIT TEN

You will return to the office for Visit 10 Three days after Visit Nine. At Visit 10 treatment to the leg test sites will end. You will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert skin grader will assess the condition of your skin and non-invasive measurements of the leg test sites will be taken. The expert grader will assess the condition of your arm skin test sites using a Wood's

lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

VISITS ELEVEN & TWELVE

You will return to the office for Visit 11 two days after Visit 10, then again two days after Visit 11 for Visit 12. At these visits you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert skin grader will assess the condition of your skin and non-invasive measurements of the leg test sites will be taken. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment.

VISIT THIRTEEN

You will return to the office for Visit 13 three days after Visit 12. At Visit 13 you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert skin grader will assess the condition of your skin and non-invasive measurements of the leg test sites will be taken. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

VISITS FOURTEEN & FIFTEEN

You will return to the office for Visit 14 two days after Visit 13, then again two days after Visit 14 for Visit 15. At these visits you will inform the study staff of medication changes and/or problems that may have occurred since your last visit. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment.

VISIT SIXTEEN

You will return to the office for Visit 16 three days after Visit 15. At Visit 16 you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

VISITS SEVENTEEN & EIGHTEEN

You will return to the office for Visit 17 two days after Visit 16, then again two days after Visit 17 for Visit 18. At these visits you will inform the study staff of medication changes and/or problems that may have occurred since your last visit. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment.

VISIT NINETEEN

You will return to the office for Visit 19 three days after Visit 18 for your final study visit. At Visit 19 you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment.

RISKS

The product being studied is a non-prescription treatment, not a drug. At this time, there are no known side effects of using this non-prescription treatment. It is possible that you may experience some skin irritation from the treatment or the dressings.

BENEFITS

You may or may not benefit from your participation in this study. The treatment may or may not improve your dry skin symptoms. The information gained from this study may benefit others with problematic skin symptoms.

ALTERNATIVE TREATMENTS

You do not have to participate in this research study to receive treatment. There are standard therapies available, which the study staff will discuss with you.

COST TO PARTICIPATE

There will be no costs to you for participating in this research study.

PAYMENT FOR PARTICIPATION

You will be compensated for your participation in this research study in the amount of three hundred dollars ($300.00) to defray transportation expenses. You will be paid in full at the completion of your participation in the study. If you do not successfully complete the entire study, you will be paid based on the following pro-rated basis:

$5.00 Complete Visit 1 but not accepted into study
$25.00 per visit completed for Visits 2-5
$5.00 for completing Visit 6
$10.00 per visit completed for Visits 7-9
$25.00 per visit completed for Visits 10-13
$10.00 per visit completed for Visits 14-19

All payments will be by check, within two weeks of your study participation termination.

COMPENSATION FOR INJURY

In the event you are injured as a result of your participation in this study, KGL Laboratories – Skin Study Center will provide or arrange for medical treatment as needed. 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 physician at KGL, Inc. at no cost to you. No additional compensation is available. You will not lose any of your legal rights by signing this consent form.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, it will not in any way harm your relations with your doctors or with KGL Laboratories – Skin Study Center. You are free to stop participating in the study if you change your mind at any time. This will not harm your relations with your doctors or with KGL Laboratories – Skin Study Center. Should you decide against participation, you will not be denied access to other available treatments for your skin condition.

You will be notified of significant new findings that may affect your treatment or your willingness to continue in this study. Your participation may also be ended without your consent if the study doctor feels that it is in your best interest, if you do not follow the study procedures or if AkPharma, Inc. cancels the study. If the study doctor ends your participation, or if you decide not to continue, you will be asked to come to the office to complete the procedures that would normally be done at the final study visit.

CONFIDENTIALITY

The records of this study will be kept confidential, except as required by law. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Your record for this study may, however, be reviewed by AkPharma, Inc., KGL Laboratories - Skin Study Center, representatives of the Food and Drug Administration (FDA), or other governmental agencies, or by the St. Davids Human Research Review Board an Institutional Review Board. An Institutional Review Board is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's safety and welfare in mind.

QUESTIONS

If you have questions relating to this research study, or to report a research related injury, you may contact:

Dr. James J. Leyden or Dr. Gary L. Grove
KGL Laboratories – Skin Study Center
505 Parkway
Broomall, PA 19008
Daytime telephone: 610-544-1715

After hours telephone: 610-251-9775 – Dr. Leyden
610-358-2381 – Dr. Grove

If you have questions about your rights as a research subject, you may call:

St. Davids Human Research Review Board at 877-398-5012 (toll-free)

INFORMED CONSENT FORM

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SPONSOR: AkPharma, Inc

PRINCIPAL INVESTIGATOR: James J. Leyden, M.D.
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610-544-1715
After hours: Dr. Grove: 610-358-2381
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- Pregnant or breast feeding.
- Major psychiatric disorder within the past two years not controlled by a stable dose of medication

for the last 6 months.

- Alcohol or substance abuse within the past two years.
- Participation in any clinical trial within the past 3 months.
- Known allergy or hypersensitivity to calcium supplements.
- Known allergy or hypersensitivity to dansyl chloride

An expert skin grader will assess the condition of your skin. You will also complete a questionnaire to determine how you feel about your skin condition. We will ask you what medication(s), both prescription and over-the-counter, you are now taking. If there are any changes in your medications, or you become pregnant, during the study, you are to tell us immediately. Your study doctor will determine your continuing status in the study.

If the doctor determines you are an appropriate candidate for the study, you will be required to discontinue the use of all "skin care" products on any parts of your body (face is exempt) through study completion.

VISIT TWO

After a one week "weaning" period from whatever skin care products you previously used, you will return for an office visit, at which your suitability for continuation in the study will be determined by Charles Zerweck, Ph.D.

If you continue in the study, you will be "randomized" into one of two treatment groups:

(1)Topical CGP applied twice daily to the LEFT arm and leg as instructed – OR -
(2) Topical CGP applied twice daily to the RIGHT arm and leg as instructed.

Being randomized means that you are put into a group by a chance process, like flipping a coin. Your chance of being assigned to either treatment group is equal. Please do not disclose this information. The doctors who assess your skin condition throughout the study won't know which group you are in, until the study is over.

You will be provided with application instructions. You will be instructed to apply the study product to the appropriate (LEFT or RIGHT) arm and leg according to the instructions provided.

You will be instructed not to apply any products, other than those provided, nor to tamper with your arms and legs in any way during the remaining study period. You will be instructed to allow the study product to be absorbed by the skin before covering again with any clothing. You will be instructed not to bathe or shower on the day of your study visits until after your evaluations have been completed by the Skin Study Center. You will be instructed to not shave your legs within 30 hours prior to each evaluative study visit.

You will be asked to complete a self-assessment questionnaire about your skin condition with the help of a study staff member. You will also be asked about any changes in medication or any problems you may have experienced since the last visit. An expert skin grader will assess the condition of your skin and non-

invasive measurements of the leg test sites will be taken.

You will be given a one week supply of study treatment. You will also be given a "Patient's Application Log" to record the time of your twice daily applications to be completed and returned at your next visit.

VISITS THREE & FOUR

You will return to the office for Visit Three one week after Visit Two; then one week after Visit Three for Visit Four. At Visit Three and at Visit Four you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert skin grader will assess the condition of your skin and non-invasive measurements of the leg test sites will be taken. You will bring your completed "Patient's Application Log" to these visits along with your remaining study treatment. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

VISITS FIVE, SIX & SEVEN

You will return to the office for Visit Five one week after Visit Four. You will bring your completed "Patient's Application Log" to these visits along with your remaining study treatment. At Visit Five treatment to the arm test sites will be temporarily suspended. The arm test sites will be stained using a suspension of 5% Dansyl Chloride in white petrolatum and covered with a dressing. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

Visit Six will be six hours after Visit Five. At Visit 6, a second application of the dye will be made and the dressings renewed.

Visit Seven will be scheduled ~~two~~ one days after Visit Six. At Visit Seven, the dressings will be removed and the test sites will be thoroughly washed with soap and water. After being patted dry, each arm test site will be examined under a Wood's lamp and the acceptability of staining determined by Dr. Charles Zerweck. If Dr. Zerweck determines that the UV staining is not acceptable then the dansyl patches will be reapplied and you will be required to return to the office six hours later that day for acceptability. Study product application will resume on the evening the dressings are removed and will continue twice daily thereafter.

VISITS EIGHT & NINE

You will return to the office for Visit Eight one day after Visit Seven, then again two days after Visit Eight for Visit Nine. At these visits you will inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your remaining study treatment.

VISIT TEN

You will return to the office for Visit 10 Three days after Visit Nine. At Visit 10 treatment to the leg test sites will end. You will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert skin grader will assess the condition of your skin and non-invasive measurements of the leg test sites will be taken. The expert grader will assess the condition of your arm skin test sites using a Wood's

lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

VISITS ELEVEN & TWELVE

You will return to the office for Visit 11 two days after Visit 10, then again two days after Visit 11 for Visit 12. At these visits you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert skin grader will assess the condition of your skin and non-invasive measurements of the leg test sites will be taken. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment.

VISIT THIRTEEN

You will return to the office for Visit 13 three days after Visit 12. At Visit 13 you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. An expert skin grader will assess the condition of your skin and non-invasive measurements of the leg test sites will be taken. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

VISITS FOURTEEN & FIFTEEN

You will return to the office for Visit 14 two days after Visit 13, then again two days after Visit 14 for Visit 15. At these visits you will inform the study staff of medication changes and/or problems that may have occurred since your last visit. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment.

VISIT SIXTEEN

You will return to the office for Visit 16 three days after Visit 15. At Visit 16 you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment. You will be given a new one week supply of study treatment and a "Patient's Application Log" to take home with you.

VISITS SEVENTEEN & EIGHTEEN

You will return to the office for Visit 17 two days after Visit 16, then again two days after Visit 17 for Visit 18. At these visits you will inform the study staff of medication changes and/or problems that may have occurred since your last visit. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment.

VISIT NINETEEN

You will return to the office for Visit 19 three days after Visit 18 for your final study visit. At Visit 19 you will be asked to complete a self-assessment questionnaire about your skin condition and inform the study staff of medication changes and/or problems that may have occurred since your last visit. The expert grader will assess the condition of your arm skin test sites using a Wood's lamp. You will bring your completed "Patient's Application Log" to these visits along with your supply of study treatment.

RISKS

The product being studied is a non-prescription treatment, not a drug. At this time, there are no known side effects of using this non-prescription treatment. It is possible that you may experience some skin irritation from the treatment or the dressings.

BENEFITS

You may or may not benefit from your participation in this study. The treatment may or may not improve your dry skin symptoms. The information gained from this study may benefit others with problematic skin symptoms.

ALTERNATIVE TREATMENTS

You do not have to participate in this research study to receive treatment. There are standard therapies available, which the study staff will discuss with you.

COST TO PARTICIPATE

There will be no costs to you for participating in this research study.

PAYMENT FOR PARTICIPATION

You will be compensated for your participation in this research study in the amount of three hundred dollars ($300.00) to defray transportation expenses. You will be paid in full at the completion of your participation in the study. If you do not successfully complete the entire study, you will be paid based on the following pro-rated basis:

$5.00 Complete Visit 1 but not accepted into study
$25.00 per visit completed for Visits 2-5
$5.00 for completing Visit 6
$10.00 per visit completed for Visits 7-9
$25.00 per visit completed for Visits 10-13
$10.00 per visit completed for Visits 14-19

All payments will be by check, within two weeks of your study participation termination.

COMPENSATION FOR INJURY

In the event you are injured as a result of your participation in this study, KGL Laboratories – Skin Study Center will provide or arrange for medical treatment as needed. 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 physician at KGL, Inc. at no cost to you. No additional compensation is available. You will not lose any of your legal rights by signing this consent form.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, it will not in any way harm your relations with your doctors or with KGL Laboratories – Skin Study Center. You are free to stop participating in the study if you change your mind at any time. This will not harm your relations with your doctors or with KGL Laboratories – Skin Study Center. Should you decide against participation, you will not be denied access to other available treatments for your skin condition.

You will be notified of significant new findings that may affect your treatment or your willingness to continue in this study. Your participation may also be ended without your consent if the study doctor feels that it is in your best interest, if you do not follow the study procedures or if AkPharma, Inc. cancels the study. If the study doctor ends your participation, or if you decide not to continue, you will be asked to come to the office to complete the procedures that would normally be done at the final study visit.

CONFIDENTIALITY

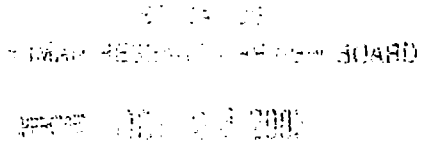
The records of this study will be kept confidential, except as required by law. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Your record for this study may, however, be reviewed by AkPharma, Inc., KGL Laboratories - Skin Study Center, representatives of the Food and Drug Administration (FDA), or other governmental agencies, or by the St. Davids Human Research Review Board an Institutional Review Board. An Institutional Review Board is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's safety and welfare in mind.

QUESTIONS

If you have questions relating to this research study, or to report a research related injury, you may contact:

Dr. James J. Leyden or Dr. Gary L. Grove
KGL Laboratories – Skin Study Center
505 Parkway
Broomall, PA 19008
Daytime telephone: 610-544-1715

After hours telephone: 610-251-9775 – Dr. Leyden
610-358-2381 – Dr. Grove



If you have questions about your rights as a research subject, you may call:

St. Davids Human Research Review Board at 877-398-5012 (toll-free)

CONSENT

I have read the above consent form. I have asked any questions I had and those questions have been answered.. I agree to be in this study. Dr. Leyden or his staff will give me a signed copy of this form.

_____
Patient's Printed Name

_____ _____
Patient's Signature Date

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Investigator's Signature Date

Appendix E

Randomization Schedule

Randomization Schedule KGL #5305

#	Code	Right	Left
1	R157	No Rx	Rx
2	G227	Rx	No Rx
3	C340	Rx	No Rx
4	M025	No Rx	Rx
5	M691	No Rx	Rx
6	T042	Rx	No Rx
7	G114	Rx	No Rx
8	J004	No Rx	Rx
9	K048	Rx	No Rx
10	D017	No Rx	Rx
11	N076	No Rx	Rx
12	C294	Rx	No Rx
13	H176	Rx	No Rx
14	S279	No Rx	Rx
15	E009	Rx	No Rx
16	F010	No Rx	Rx
17	D283	No Rx	Rx
18	P108	Rx	No Rx
19	W028	Rx	No Rx
20	C219	No Rx	Rx

Appendix F

Panelist Instructions

Instructions for Application of Topical CGP to Skin

1- Have portions of skin to be treated freshly washed and dried. Ideally, skin can be "still a little moist" from the washing.

2- **Thoroughly mix contents of bottle by shaking** several times in a direction from top to bottom .

3- Apply 2 or 3 small dabs (about the size of peas) of the cream, directly to the skin. -OR- If direct application is not feasible apply product to your fingertips and apply from fingertips to the leg and arm areas as instructed.

4- Using the fingertips of one hand, rub the cream thoroughly into the skin, using up and down, as well as circular motions. The cream will 'disappear' into the skin and the moisture will evaporate in such a way that the rubbing becomes dry.

5- The amount of cream used should be sufficient so that when dry, there is no more than a very thin coat of dry white residue remaining over the treated area; if needed, apply slightly more, and use a larger dab next time. If too much remaining, apply slightly less next time.

6- Hold your fingertips under tap water and wet them slightly; shake off all excess moisture so that the fingertips are barely wet. Again, rub the fingertips on the same area you just coated with the cream. This will provide a slight bit of additional moisture to assure adequate absorption of the remaining white residue. Let treated skin air dry -OR- if necessary, you can DAB DRY with a towel – DO NOT RUB .

7- When the skin dries after Step 6, there should be little or no whitish residue seen.

8- Do not wash off until the new application time. Follow the rest of the printed directions given below:

Your ID Number is : **0XX**

You are assigned to apply this study product to:

L –or- R leg (calf area - ankle to knee) and **L – or- R** arm (upper-inner, inside of bicep) as instructed.

Appendix G

Sample Diary Form

PRODUCT USE DIARY

KGL #5305 #1

S# _____ CODE: ___ ___ ___ ___ NAME _____

If you have any questions about the product or product usage please call 610-544-1715.
Please keep this with your product and fill in the times that it was used.
(Use a pen - not a pencil - to complete this form)
REMEMBER YOU MAY NOT GET TAN DURING THE STUDY OR YOU WILL BE DROPPED

DAY	DATE	TIME OF PRODUCT APPLICATIONS AM	PM	DAY	DATE	TIME OF PRODUCT APPLICATIONS AM	PM
Mon.	Nov 3, 2003 [visit 2]	_____	_____	Fri.	Nov 14, 2003	_____	_____
		May shave AFTER visit					
Tue.	Nov 4, 2003	_____	_____	Sat.	Nov 15, 2003	_____	_____
						MUST SHAVE	
Wed.	Nov 5, 2003	_____	_____	Sun.	Nov 16, 2003	_____	_____
						Don't shave	
Thu.	Nov 6, 2003	_____	_____	Mon.	Nov 17, 2003 [visit 4]	_____	_____
Fri.	Nov 7, 2003	_____	_____	Tue.	Nov 18, 2003	May shave AFTER visit	
						_____	_____
Sat.	Nov 8, 2003	_____	_____	Wed.	Nov 19, 2003	_____	_____
		MUST SHAVE					
Sun.	Nov 9, 2003	_____	_____	Thu.	Nov 20, 2003	_____	_____
		Don't shave					
Mon.	Nov 10, 2003 [visit 3]	_____	_____	Fri.	Nov 21, 2003	_____	_____
		May shave AFTER visit					
Tue.	Nov 11, 2003	_____	_____	Sat.	Nov 22, 2003	_____	_____
						MUST SHAVE	
Wed.	Nov 12, 2003	_____	_____	Sun.	Nov 23, 2003	_____	_____
						Don't shave	
Thu.	Nov 13, 2003	_____	_____				

Please do not apply your product when you come to the lab.
PLEASE BRING PRODUCTS WITH YOU TO EACH VISIT

VISIT 3 – Monday, Nov 10 at _____for Grades and Instruments.

VISIT 4 – Monday, Nov 17 at _____for Grades and Instruments.

VISIT 5 – Monday, Nov 24 at _____for Grades and Instruments and patches applied.
VISIT 6 – Return Monday afternoon at _____to have patches renewed.

EMERGENCY #'s: Dr. James Leyden 610-251-9775
Dr. Gary Grove 610-358-2381
Dr. Kays Kaidbey 215-238-1225

PLEASE RETURN ALL PRODUCTS TO THE SKIN STUDY CENTER
I CERTIFY THAT I HAVE COMPLETED THE TREATMENTS AS REQUIRED.

_____ _____
SIGNATURE OF PANELIST DATE

Appendix H

Sample Expert Grader Form

EXPERT GRADER ASSESSMENT
LEG TEST SITES

KGL #5305

_____ ID CODE ___ ___ ___ ___

VISIT: (CIRCLE)

-1 WEEK	DAY 1	DAY 8
DAY 15	DAY 22	DAY 29 / REGRESSION 0
DAY 31 / REGRESSION 2	DAY 33 / REGRESSION 4	DAY 36 / REGRESSION 7

	RIGHT LEG	LEFT LEG
DRYNESS [0 – 8 scale]		
TEXTURE [0 – 8 scale]		
CREPINESS [0 – 9 scale]		
OVERALL PHOTOAGING [0 – 9 scale]		

	DRYNESS			TEXTURE
0	None		0	Normal, smooth skin
1-2	Slight flaking or occasional small lifting scales may be present		1-2	Slight, but definite roughness
3-4	Moderate flaking/scaling		3-4	Moderate roughness
5-6	Marked scaling, slight fissuring, heavy cracking and lifting scales		5-6	Marked roughness
7-8	Severe scaling, fissuring, cracking		7-8	Very marked roughness

	CREPINESS			OVERALL PHOTOAGING
0	Smooth, normal, healthy skin		0	None
1-3	Small circular fine lines, may not be real obvious at first glance; see more with twisting of the skin; less than 25%		1-3	Mild
4-6	Obvious lined pattern, may look like circular lines/may look "puffy"; more than 25% coverage but to a lesser degree		4-6	Moderate
7-9	Up to 100% coverage of the outer leg; very obvious, well demarcated; long, "puffy"(depth), longitudinal lines		7-9	Severe

Ties will be broken by forcing the Expert Grader to add 0.1 to that site which he thinks might be worse, except prior to beginning treatment (–1 week & Day 0).

Appendix I

Sample Self-Assessment Form

SELF-ASSESSMENT
LEG TEST SITES

KGL #5305

_____ ID CODE ___ ___ ___ ___

VISIT:
(CIRCLE)

-1 WEEK | DAY 1 | DAY8

DAY 15 | DAY 22 | DAY 29 / REGRESSION 0

DAY 31 / REGRESSION 2 | DAY 33 / REGRESSION 4 | DAY 36 / REGRESSION 7

	RIGHT LEG	**LEFT LEG**
DRYNESS		
ROUGHNESS		
TIGHTNESS		
ITCHING		
BURNING/STINGING		

0 = NONE
1 = SLIGHT
2 = MODERATE
3 = SEVERE

IF SCORES ARE TIED, THERE WILL BE A FORCED CHOICE AND O.1 SHOULD BE ADDED TO SIDE THAT IS WORSE.

Appendix J

Demographic Data

DEMOGRAPHIC DATA

#	I D	AGE	SEX	INITIALS
1	R157	47	F	KDR
2	G227	65	F	P-G
3	C340	62	F	G-C
4	M025	51	F	VLM
5	M691	64	F	MMM
6	T042	51	F	JMT
7	G114	48	F	G-G
8	J004	61	F	R-J
9	K048	48	F	D-K
10	D017	51	F	DAD
11	N076	56	F	JMN
12	C294	54	F	KJC
13	H176	50	F	DAH
14	S279	53	F	JMS
15	E009	48	F	SME
16	F010	63	F	SAF
17	D283	62	F	STD
18	P108	65	F	CWP
19	W028	59	F	BMW
20	C219	65	F	HDC

Appendix K

Expert Grader Dryness Data

Sorted Data

KGL #5305

EXPERT GRADER ASSESSMENT OF DRYNESS
(Scale: 0 = None to 7-8 = Severe scaling, fissuring, cracking)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	6.0	6.0	6.0	6.0	5.0	6.0	4.0	5.0	4.0	6.0
2	G227										
3	C340	4.0	4.0	5.0	5.0	7.0	6.0	7.0	7.1	6.0	7.0
4	M025	6.0	6.0	5.0	5.0	5.0	4.0	4.0	3.0	3.0	4.0
5	M691	6.0	6.0	6.0	6.0	6.0	4.0	7.0	6.0	6.0	5.0
6	T042	4.0	4.0	5.0	5.0	5.0	5.1	5.0	6.0	4.0	5.0
7	G114	6.0	6.0	6.0	6.0	6.0	6.1	5.0	6.0	5.0	6.0
8	J004										
9	K048	5.0	5.0	5.0	5.0	5.1	5.0	5.0	6.0	5.1	5.0
10	D017	3.0	3.0	4.0	4.0	4.0	5.0	3.0	4.0	4.1	4.0
11	N076	5.0	5.0	4.0	4.0	4.0	5.0	5.0	4.0	4.0	5.0
12	C294	5.0	5.0	5.0	5.0	5.0	6.0	5.0	6.0	4.0	6.0
13	H176	4.0	4.0	4.0	4.0	6.0	6.1	3.0	4.0	4.0	5.0
14	S279	6.0	6.0	5.0	5.0	6.0	5.0	6.0	5.0	6.1	6.0
15	E009	3.0	3.0	3.0	3.0	3.0	3.1	4.1	4.0	3.0	4.0
16	F010	6.0	6.0	6.0	6.0	5.0	6.0	4.0	5.0	5.0	4.0
17	D283	6.0	6.0	6.0	6.0	6.0	5.0	5.1	5.0	5.0	6.0
18	P108	5.0	5.0	5.0	5.0	5.1	5.0	3.0	3.1	5.0	4.0
19	W028	5.0	5.0	4.0	4.0	5.0	4.0	4.1	4.0	5.0	4.0
20	C219	7.0	7.0	6.0	6.0	6.0	5.0	6.0	5.0	6.0	4.0
Mean		***5.11***	***5.11***	***5.00***	***5.00***	***5.23***	***5.08***	***4.74***	***4.90***	***4.68***	***5.00***
Std Dev		***1.13***	***1.13***	***0.91***	***0.91***	***0.94***	***0.87***	***1.22***	***1.13***	***0.98***	***0.97***
Paired T-Test		***1.0000***		***1.0000***		***0.4864***		***0.4379***		***0.2562***	

EXPERT GRADER ASSESSMENT OF DRYNESS
(Scale: 0 = None to 7-8 = Severe scaling, fissuring, cracking)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	5.0	5.1	4.1	4.0	4.0	5.0	5.0	5.1
2	G227								
3	C340	6.0	5.0	6.0	5.0	7.0	6.0	7.0	6.0
4	M025	3.0	5.0	3.0	4.0	4.0	4.1	4.0	4.1
5	M691	6.0	4.0	6.1	6.0			6.0	4.0
6	T042	4.0	5.0	4.0	5.0	4.0	5.0	5.0	6.0
7	G114	5.0	6.0	6.1	6.0	4.0	5.0	6.1	6.0
8	J004								
9	K048	4.0	5.0	5.0	6.0			5.0	6.0
10	D017	5.0	5.1	6.0	6.1			5.0	4.0
11	N076	5.0	4.0	4.1	4.0			6.0	4.0
12	C294	4.0	6.0	5.0	6.0	5.0	6.0	6.1	6.0
13	H176	4.0	5.0	6.1	6.0			6.0	5.0
14	S279	6.1	6.0	7.0	6.0	6.1	6.0	6.0	5.0
15	E009	3.0	4.0	4.1	4.0	4.0	3.0	5.0	3.0
16	F010	6.0	5.0	6.0	5.0				
17	D283	4.0	5.0	4.0	4.1	4.0	4.1	4.0	4.1
18	P108	5.0	4.0	6.1	6.0	5.1	5.0	5.0	6.0
19	W028	4.0	4.1	5.0	4.0	4.0	3.0	4.0	4.1
20	C219	6.0	5.0	5.0	6.0	5.0	6.0	5.1	5.0
Mean		***4.73***	***4.91***	***5.15***	***5.18***			***5.31***	***4.91***
Std Dev		***1.03***	***0.67***	***1.08***	***0.92***			***0.86***	***0.98***
Paired T-Test		***0.5206***		***0.8738***				***0.1165***	

Appendix L

Expert Grader Texture Data

Sorted Data KGL #5305

EXPERT GRADER ASSESSMENT OF TEXTURE
(Scale: 0 = Normal, smooth skin to 7-8 = Very marked roughness)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	6.0	6.0	5.0	5.0	6.0	7.0	4.0	5.0	4.0	5.0
2	G227										
3	C340	6.0	6.0	6.0	6.0	7.0	6.0	8.0	7.0	7.0	7.1
4	M025	4.0	4.0	4.0	4.0	4.1	4.0	4.0	3.0	3.0	3.1
5	M691	5.0	5.0	6.0	6.0	5.1	5.0	7.0	8.0	6.1	6.0
6	T042	4.0	4.0	4.0	4.0	4.1	4.0	4.0	5.0	5.1	5.0
7	G114	6.0	6.0	6.0	6.0	5.1	5.0	5.0	6.0	6.1	6.0
8	J004										
9	K048	6.0	6.0	6.0	6.0	6.1	6.0	5.0	6.0	5.0	5.1
10	D017	5.0	5.0	4.0	4.0	4.1	4.0	4.0	4.1	4.1	4.0
11	N076	5.0	5.0	4.0	4.0	4.0	5.0	5.0	4.0	3.0	4.0
12	C294	5.0	5.0	5.0	5.0	5.0	6.0	6.0	7.0	6.1	6.0
13	H176	5.0	5.0	4.0	4.0	5.0	5.1	4.0	4.1	4.0	5.0
14	S279	6.0	6.0	5.0	5.0	6.0	6.1	7.0	7.1	7.0	6.0
15	E009	4.0	4.0	4.0	4.0	4.0	3.0	5.0	5.1	5.1	5.0
16	F010	7.0	7.0	7.0	7.0	6.0	7.0	4.0	5.0	6.1	6.0
17	D283	6.0	6.0	6.0	6.0	6.0	5.0	5.0	5.1	5.0	6.0
18	P108	4.0	4.0	4.0	4.0	5.0	4.0	3.0	4.0	5.0	4.0
19	W028	4.0	4.0	4.0	4.0	4.1	4.0	3.1	3.0	3.0	2.0
20	C219	7.0	7.0	6.0	6.0	6.0	5.0	7.0	5.0	7.0	5.0
Mean		***5.28***	***5.28***	***5.00***	***5.00***	***5.15***	***5.07***	***5.01***	***5.19***	***5.09***	***5.02***
Std Dev		***1.02***	***1.02***	***1.03***	***1.03***	***0.94***	***1.12***	***1.45***	***1.42***	***1.36***	***1.24***
Paired T-Test		***1.0000***		***1.0000***		***0.6326***		***0.3963***		***0.6866***	

SORTED DATA KGL #5305

EXPERT GRADER ASSESSMENT OF TEXTURE
(Scale: 0 = Normal, smooth skin to 7-8 = Very marked roughness)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	4.0	5.0	4.0	5.0	4.0	5.0	6.1	6.0
2	G227								
3	C340	7.0	6.0	7.1	7.0	7.0	6.0	7.0	6.0
4	M025	3.0	5.0	4.0	4.1	4.1	4.0	4.0	4.1
5	M691	5.1	5.0	6.0	6.1			6.1	6.0
6	T042	4.0	5.0	5.1	5.0	4.0	4.1	5.0	6.0
7	G114	6.0	7.0	7.0	7.1	6.0	6.1	6.0	6.1
8	J004								
9	K048	6.0	5.0	6.0	7.0			6.0	7.0
10	D017	4.0	5.0	6.0	6.1			4.0	5.0
11	N076	4.1	4.0	4.0	5.0			5.1	5.0
12	C294	4.0	6.0	5.0	6.0	5.0	6.0	6.0	7.0
13	H176	5.0	6.0	6.1	6.0			6.0	5.0
14	S279	6.0	6.1	7.1	7.0	6.0	6.1	6.1	6.0
15	E009	5.0	4.0	5.0	4.0	4.0	3.0	4.0	3.0
16	F010	6.0	6.1	7.0	6.0				
17	D283	4.0	5.0	5.0	5.1	4.0	5.0	4.0	4.1
18	P108	6.0	5.0	6.0	5.0	7.0	6.0	6.1	6.0
19	W028	4.1	4.0	5.0	4.0	3.1	3.0	4.0	3.0
20	C219	6.1	6.0	6.0	6.1	6.0	6.1	5.0	6.0
Mean		***4.97***	***5.29***	***5.63***	***5.64***			***5.32***	***5.37***
Std Dev		***1.11***	***0.84***	***1.05***	***1.04***			***1.00***	***1.21***
Paired T-Test		***0.1793***		***0.9463***				***0.7996***	

Appendix M

Expert Grader Crepiness Data

EXPERT GRADER ASSESSMENT OF CREPINESS

(Scale: 0 = Smooth, normal, healthy skin to

7-9 = Up to 100% coverage of the outler leg; very obvious, well demarcated; long, "puffy" [depth], longitudinal lines)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	5.0	5.0	5.0	5.0	5.0	6.0	5.0	6.0	5.0	6.0
2	G227										
3	C340	6.0	6.0	7.0	7.0	8.0	7.0	8.0	7.0	8.0	8.1
4	M025	4.0	4.0	5.0	5.0	6.1	6.0	4.0	3.0	4.0	4.1
5	M691	8.0	8.0	8.0	8.0	8.1	8.0	7.1	7.0	8.1	8.0
6	T042	4.0	4.0	4.0	4.0	5.0	4.0	4.0	5.0	4.1	4.0
7	G114	5.0	5.0	5.0	5.0	6.0	6.1	6.0	6.1	6.1	6.0
8	J004										
9	K048	4.0	4.0	5.0	5.0	5.0	5.1	5.0	6.0	5.0	6.0
10	D017	5.0	5.0	5.0	5.0	5.1	5.0	5.0	5.1	5.0	5.1
11	N076	5.0	5.0	6.0	6.0	6.0	7.0	5.0	5.1	5.0	5.1
12	C294	6.0	6.0	6.0	6.0	5.0	6.0	6.0	7.0	6.0	7.0
13	H176	4.0	4.0	5.0	5.0	5.0	6.0	4.0	5.0	4.0	5.0
14	S279	7.0	7.0	7.0	7.0	7.0	6.0	8.0	8.1	8.0	7.0
15	E009	3.0	3.0	3.0	3.0	4.1	4.0	5.1	5.0	5.0	5.1
16	F010	6.0	6.0	6.0	6.0	7.1	7.0	7.0	7.1	7.1	7.0
17	D283	7.0	7.0	8.0	8.0	8.1	8.0	7.1	7.0	7.0	7.1
18	P108	6.0	6.0	6.0	6.0	6.1	6.0	5.1	5.0	5.1	5.0
19	W028	4.0	4.0	4.0	4.0	4.1	4.0	4.0	4.1	4.1	4.0
20	C219	7.0	7.0	7.0	7.0	7.1	7.0	7.1	7.0	7.1	7.0
Mean		***5.33***	***5.33***	***5.67***	***5.67***	***5.99***	***6.01***	***5.69***	***5.87***	***5.76***	***5.92***
Std Dev		***1.37***	***1.37***	***1.37***	***1.37***	***1.31***	***1.23***	***1.38***	***1.30***	***1.45***	***1.32***
Paired T-Test		***1.0000***		***1.0000***		***0.9142***		***0.2563***		***0.2092***	

SORTED DATA

KGL #5305

EXPERT GRADER ASSESSMENT OF CREPINESS

(Scale: 0 = Smooth, normal, healthy skin to

7-9 = Up to 100% coverage of the outler leg; very obvious, well demarcated; long, "puffy" [depth], longitudinal lines)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	4.0	5.0	5.0	5.1	5.0	5.1	5.1	5.0
2	G227								
3	C340	8.1	8.0	8.1	8.0	8.1	8.0	8.1	8.0
4	M025	4.0	4.1	4.0	4.1	4.0	4.1	5.0	5.1
5	M691	8.0	7.0	8.1	8.0			8.1	8.0
6	T042	3.0	4.0	4.0	4.1	3.1	3.0	4.0	4.1
7	G114	7.0	7.1	7.0	7.1	5.0	6.0	5.0	5.1
8	J004								
9	K048	5.0	6.0	5.0	6.0			5.0	6.0
10	D017	6.0	6.1	5.1	5.0			4.1	4.0
11	N076	6.1	6.0	6.0	6.1			6.0	5.0
12	C294	7.0	7.1	7.0	7.1	7.0	7.1	6.0	7.0
13	H176	5.0	6.0	5.1	5.0			5.1	5.0
14	S279	8.0	7.0	7.1	7.0	7.0	7.1	7.1	7.0
15	E009	5.0	6.0	4.1	4.0	4.1	4.0	5.0	4.0
16	F010	7.0	7.1	7.1	7.0				
17	D283	7.0	8.0	7.0	7.1	8.0	8.1	7.0	8.0
18	P108	6.1	6.0	6.1	6.0	7.0	6.0	6.0	6.1
19	W028	4.0	4.1	4.1	4.0	4.1	4.0	4.1	4.0
20	C219	6.0	7.0	6.0	7.0	6.0	7.0	6.0	6.1
Mean		***5.91***	***6.20***	***5.88***	***5.98***			***5.69***	***5.74***
Std Dev		***1.54***	***1.24***	***1.39***	***1.39***			***1.28***	***1.44***
Paired T-Test		***0.0778***		***0.2307***				***0.7351***	

Appendix N

Expert Grader Overall Photodamage Data

EXPERT GRADER ASSESSMENT OF OVERALL PHOTODAMAGE
(Scale: 0 = None to 7-9 = Severe)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	5.0	5.0	5.0	5.0	4.0	5.0	4.0	5.0	5.0	6.0
2	G227										
3	C340	6.0	6.0	7.0	7.0	8.0	7.0	7.0	7.1	7.0	7.1
4	M025	4.0	4.0	5.0	5.0	5.1	5.0	4.1	4.0	4.0	4.1
5	M691	8.0	8.0	8.0	8.0	8.1	7.0	7.0	7.1	8.1	8.0
6	T042	4.0	4.0	4.0	4.0	4.1	4.0	4.0	5.0	4.0	4.1
7	G114	5.0	5.0	5.0	5.0	5.1	5.0	5.0	6.0	5.0	6.0
8	J004										
9	K048	4.0	4.0	4.0	4.0	5.1	5.0	5.0	6.0	5.0	5.1
10	D017	4.0	4.0	4.0	4.0	4.1	4.0	4.0	4.1	4.0	4.1
11	N076	5.0	5.0	4.0	4.0	4.0	5.0	5.0	4.0	5.0	5.1
12	C294	6.0	6.0	6.0	6.0	6.0	6.1	6.0	7.0	6.0	7.0
13	H176	4.0	4.0	4.0	4.0	5.0	5.1	4.0	5.0	4.0	5.0
14	S279	6.0	6.0	6.0	6.0	7.0	6.0	7.0	7.1	7.0	6.0
15	E009	3.0	3.0	3.0	3.0	4.1	4.0	5.1	5.0	5.0	5.1
16	F010	7.0	7.0	6.0	6.0	6.0	7.0	6.0	7.0	7.1	7.0
17	D283	7.0	7.0	7.0	7.0	7.1	7.0	7.1	7.0	7.0	7.1
18	P108	6.0	6.0	6.0	6.0	6.1	6.0	5.0	5.1	5.1	5.0
19	W028	4.0	4.0	4.0	4.0	4.1	4.0	4.1	4.0	4.1	4.0
20	C219	7.0	7.0	7.0	7.0	7.1	7.0	7.0	6.0	7.0	6.0
Mean		***5.28***	***5.28***	***5.28***	***5.28***	***5.56***	***5.51***	***5.36***	***5.64***	***5.52***	***5.66***
Std Dev		***1.41***	***1.41***	***1.41***	***1.41***	***1.42***	***1.15***	***1.23***	***1.21***	***1.35***	***1.23***
Paired T-Test		***1.0000***		***1.0000***		***0.7315***		***0.0909***		***0.3464***	

SORTED DATA KGL #5305

EXPERT GRADER ASSESSMENT OF OVERALL PHOTODAMAGE
(Scale: 0 = None to 7-9 = Severe)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	4.0	5.0	5.0	5.1	5.0	5.1	5.1	5.0
2	G227								
3	C340	7.1	7.0	7.1	7.0	7.1	7.0	7.1	7.0
4	M025	4.0	4.1	4.0	4.1	4.0	4.1	4.0	4.1
5	M691	8.0	7.0	8.1	8.0			8.1	8.0
6	T042	3.0	4.0	4.0	4.1	4.1	4.0	4.0	4.1
7	G114	7.0	7.1	6.0	6.1	6.0	6.1	5.0	5.1
8	J004								
9	K048	5.0	6.0	5.0	6.0			5.0	6.0
10	D017	5.0	5.1	5.1	5.0			4.1	4.0
11	N076	5.1	5.0	5.0	5.1			6.0	5.0
12	C294	6.0	7.0	7.0	7.1	7.0	7.1	7.0	7.1
13	H176	5.0	6.0	5.1	5.0			5.1	5.0
14	S279	7.1	7.0	7.1	7.0	6.0	6.1	6.1	6.0
15	E009	5.0	5.1	4.1	4.0	4.1	4.0	5.0	4.0
16	F010	7.0	7.1	7.1	7.0				
17	D283	7.0	7.1	7.0	7.1	7.0	7.1	7.0	7.1
18	P108	5.1	5.0	6.1	6.0	6.1	6.0	6.0	6.1
19	W028	4.0	4.1	4.1	4.0	4.1	4.0	4.1	4.0
20	C219	7.0	7.1	7.0	7.1	7.0	7.1	7.0	7.1
Mean		***5.63***	***5.88***	***5.77***	***5.82***			***5.63***	***5.57***
Std Dev		***1.43***	***1.20***	***1.33***	***1.30***			***1.28***	***1.34***
Paired T-Test		***0.0740***		***0.4210***				***0.5881***	

Appendix O

Self-Assessment Data

SELF-ASSESSMENT OF DRYNESS
(Scale: 0 = None to 3 = Severe)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	3.0	3.1	3.0	3.1	3.0	3.1	3.0	2.0	2.0	3.0
2	G227										
3	C340	2.0	2.1	2.1	2.0	2.0	1.0	2.1	2.0	2.1	2.0
4	M025	1.1	1.0	1.1	1.0	1.0	2.0	1.1	1.0	1.0	2.0
5	M691	3.0	3.1	2.0	2.1	1.0	2.0	1.0	2.0	2.1	2.0
6	T042	2.0	2.1	2.1	2.0	2.1	2.0	2.0	1.0	2.0	1.0
7	G114	2.0	2.1	2.1	2.0	2.1	2.0	2.1	2.0	2.1	2.0
8	J004										
9	K048	2.0	2.1	2.0	2.1	2.1	2.0	2.1	2.0	1.1	1.0
10	D017	1.1	1.0	1.0	2.0	1.1	1.0	2.0	2.1	2.0	1.0
11	N076	3.0	2.0	3.1	3.0	2.0	3.0	2.0	1.0	2.0	1.0
12	C294	2.0	3.0	2.0	3.0	2.0	3.0	2.0	3.0	2.0	3.0
13	H176	2.1	2.0	2.1	2.0	3.1	3.0	2.0	2.1	2.0	2.1
14	S279	3.0	2.0	2.1	2.0	3.1	3.0	2.1	2.0	3.0	2.0
15	E009	2.1	2.0	2.1	2.0	2.0	1.0	2.0	1.0	2.0	0.0
16	F010	2.1	2.0	2.0	2.1	2.0	2.1	1.0	2.0	2.1	2.0
17	D283	2.1	2.0	2.1	2.0	2.1	2.0	1.1	1.0	2.1	2.0
18	P108	3.0	3.1	2.1	2.0	2.1	2.0	2.1	2.0	2.0	1.0
19	W028	1.0	1.1	0.0	1.0	2.0	1.0	0.0	1.0	1.0	0.0
20	C219	2.1	2.0	3.0	2.0	2.0	1.0	2.0	1.0	1.0	1.1
Mean		***2.15***	***2.10***	***2.00***	***2.08***	***2.04***	***2.01***	***1.76***	***1.68***	***1.87***	***1.57***
Std Dev		***0.65***	***0.66***	***0.73***	***0.55***	***0.61***	***0.78***	***0.67***	***0.60***	***0.52***	***0.86***
Paired T-Test		***0.6260***		***0.5071***		***0.8399***		***0.6326***		***0.1395***	

SELF-ASSESSMENT OF DRYNESS
(Scale: 0 = None to 3 = Severe)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7		Day 43 Reg 14		Day 50 Reg 21	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	3.0	3.1	3.0	3.1	3.0	3.1	3.0	3.1	3.0	3.1	3.0	3.1
2	G227												
3	C340	2.1	2.0	2.1	2.0	2.1	2.0	2.1	2.0	2.0	1.0	2.1	2.0
4	M025	1.0	2.0	1.0	2.0	2.0	3.0	2.0	3.0	2.0	2.1	2.0	2.1
5	M691	2.0	1.0	2.0	1.0			2.0	1.0	2.0	1.0	2.0	1.0
6	T042	2.1	2.0	1.1	1.0	2.0	1.0	1.1	1.0	2.1	2.0	1.0	1.1
7	G114	2.0	2.1	2.1	2.0	3.1	3.0	2.1	2.0	2.1	2.0	2.1	2.0
8	J004												
9	K048	2.0	1.0	2.0	1.0			2.0	1.0	2.1	2.0	1.1	1.0
10	D017	1.0	2.0	1.0	2.0			1.0	2.0	1.0	2.0	1.0	2.0
11	N076	1.0	1.1	2.0	1.0			2.0	1.0	2.0	1.0	1.0	1.1
12	C294	2.0	3.0	2.0	3.0	2.0	3.0	2.0	3.0	2.0	3.0	2.0	3.0
13	H176	3.0	2.0	3.1	3.0			3.1	3.0	3.1	3.0	3.0	3.1
14	S279	2.0	2.1	2.1	2.0	2.1	2.0	2.1	2.0	2.1	2.0	2.1	2.0
15	E009	2.0	1.0	2.0	1.0	1.1	1.0	2.0	1.0	2.0	1.0	2.0	1.0
16	F010	1.0	2.0	2.0	2.1					2.0	2.1	2.0	1.0
17	D283	1.0	1.1	2.1	2.0	1.0	2.0	2.1	2.0	2.0	2.1	1.0	2.0
18	P108	3.0	2.0	3.1	3.0	2.0	0.0	2.0	3.0	3.0	2.0	2.1	2.0
19	W028	0.0	1.0	0.0	1.0	1.0	0.0	0.1	0.0	0.0	1.0	0.0	1.0
20	C219	2.0	1.0	1.1	1.0	2.0	1.0	1.1	1.0	2.0	1.0	2.0	1.0
Mean		***1.79***	***1.75***	***1.88***	***1.84***			***1.87***	***1.83***	***2.03***	***1.86***	***1.75***	***1.75***
Std Dev		***0.81***	***0.67***	***0.80***	***0.80***			***0.72***	***0.96***	***0.70***	***0.72***	***0.76***	***0.76***
Paired T-Test		***0.8402***		***0.8399***				***0.8140***		***0.3175***		***1.0000***	

SELF-ASSESSMENT OF ROUGHNESS
(Scale: 0 = None to 3 = Severe)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	3.0	3.1	3.0	3.1	3.0	3.1	3.0	2.0	3.0	3.1
2	G227										
3	C340	1.1	1.0	2.1	2.0	2.0	1.0	2.0	1.0	2.1	2.0
4	M025	1.1	1.0	1.1	1.0	1.0	2.0	1.1	1.0	1.0	2.0
5	M691	2.0	3.0	1.0	1.1	1.0	2.0	0.0	1.0	2.0	1.0
6	T042	2.0	2.1	1.1	1.0	2.0	1.0	2.0	1.0	2.0	1.0
7	G114	1.1	1.0	1.1	1.0	1.1	1.0	1.1	1.0	0.1	0.0
8	J004										
9	K048	2.1	2.0	2.0	2.1	2.1	2.0	2.1	2.0	2.0	1.0
10	D017	1.1	1.0	1.0	1.1	1.1	1.0	1.0	1.1	1.0	2.0
11	N076	3.0	2.0	2.1	2.0	2.0	3.0	2.0	1.0	2.0	1.0
12	C294	2.0	3.0	2.0	3.0	2.0	3.0	2.0	2.1	2.0	3.0
13	H176	1.1	1.0	1.1	1.0	3.1	3.0	2.0	2.1	1.0	2.0
14	S279	2.0	2.1	3.0	3.1	2.1	2.0	1.1	1.0	2.1	2.0
15	E009	1.1	1.0	2.1	2.0	2.0	1.0	2.0	1.0	2.0	1.0
16	F010	3.0	2.0	2.0	2.1	2.0	2.1	1.0	2.0	2.0	1.0
17	D283	2.1	2.0	2.1	2.0	2.0	2.1	2.1	2.0	2.1	2.0
18	P108	0.1	0.0	1.1	1.0	3.0	2.0	0.1	0.0	1.0	0.0
19	W028	1.0	1.1	0.0	1.0	2.0	1.0	1.0	0.0	1.0	0.0
20	C219	1.0	3.0	3.0	2.0	2.0	1.0	2.0	1.0	1.0	1.1
Mean		***1.66***	***1.74***	***1.72***	***1.76***	***1.97***	***1.85***	***1.53***	***1.24***	***1.63***	***1.40***
Std Dev		***0.82***	***0.90***	***0.83***	***0.77***	***0.63***	***0.80***	***0.77***	***0.66***	***0.70***	***0.92***
Paired T-Test		***0.6130***		***0.7050***		***0.5041***		***0.0778***		***0.2368***	

SELF-ASSESSMENT OF ROUGHNESS
(Scale: 0 = None to 3 = Severe)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7		Day 43 Reg 14		Day 50 Reg 21	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	3.0	3.1	3.0	3.1	3.0	3.1	3.0	3.1	3.0	3.1	3.0	3.1
2	G227												
3	C340	2.1	2.0	2.1	2.0	2.1	2.0	2.1	2.0	2.1	2.0	2.1	2.0
4	M025	1.0	2.0	1.0	2.0	2.0	3.0	2.0	3.0	2.0	2.1	3.0	3.1
5	M691	2.0	1.0	2.0	1.0			2.0	1.0	2.0	1.0	2.0	1.0
6	T042	1.1	1.0	1.1	1.0	2.0	1.0	1.1	1.0	1.1	1.0	1.0	1.1
7	G114	2.1	2.0	0.1	0.0	1.1	1.0	0.1	0.0	0.1	0.0	0.1	0.0
8	J004												
9	K048	2.0	1.0	2.0	1.0			2.0	1.0	1.1	1.0	1.1	1.0
10	D017	1.0	2.0	1.0	2.0			1.0	2.0	1.0	2.0	1.0	2.0
11	N076	1.0	1.1	2.0	1.0			2.0	1.0	2.0	1.0	1.0	1.1
12	C294	2.0	3.0	2.0	3.0	2.0	3.0	2.0	3.0	2.0	3.0	2.0	3.0
13	H176	3.0	2.0	2.1	2.0			2.1	2.0	2.1	2.0	2.0	2.1
14	S279	2.0	2.1	2.1	2.0	3.1	3.0	2.1	2.0	2.1	2.0	2.1	2.0
15	E009	2.0	1.0	2.0	1.0	2.0	1.0	2.0	1.0	2.0	1.0	2.0	1.0
16	F010	2.0	1.0	1.0	2.0					2.0	3.0	2.0	1.0
17	D283	1.0	1.1	2.0	2.1	2.0	2.1	2.1	2.0	2.0	2.1	1.0	2.0
18	P108	3.0	0.0	3.1	3.0	2.0	0.0	1.0	2.0	1.1	1.0	2.1	2.0
19	W028	0.0	1.0	0.0	1.0	1.0	0.0	1.1	1.0	0.0	1.0	0.0	1.0
20	C219	2.0	1.0	2.0	1.0	2.0	1.0	1.1	1.0	2.0	1.0	2.0	1.0
Mean		***1.79***	***1.52***	***1.70***	***1.68***			***1.69***	***1.65***	***1.65***	***1.63***	***1.64***	***1.64***
Std Dev		***0.81***	***0.79***	***0.84***	***0.85***			***0.68***	***0.87***	***0.76***	***0.87***	***0.84***	***0.86***
Paired T-Test		***0.2739***		***0.9039***				***0.8140***		***0.8929***		***1.0000***	

SELF-ASSESSMENT OF ITCHING
(Scale: 0 = None to 3 = Severe)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1
2	G227										
3	C340	1.0	1.1	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
4	M025	1.1	1.0	0.1	0.0	0.0	0.1	0.1	0.0	0.0	0.1
5	M691	0.0	1.0	1.0	1.1	0.0	0.1	0.0	0.1	0.1	0.0
6	T042	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
7	G114	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
8	J004										
9	K048	1.0	1.1	1.0	1.1	0.1	0.0	0.1	0.0	0.1	0.0
10	D017	0.0	0.1	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.0
11	N076	2.0	1.0	0.1	0.0	0.0	0.1	0.1	0.0	0.1	0.0
12	C294	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1
13	H176	1.1	1.0	0.1	0.0	0.1	0.0	0.0	0.1	0.0	0.1
14	S279	1.1	1.0	1.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
15	E009	2.1	2.0	2.1	2.0	0.1	0.0	1.0	0.0	2.0	0.0
16	F010	0.0	2.0	0.0	0.1	0.0	0.1	0.0	0.1	0.1	0.0
17	D283	2.1	2.0	0.1	0.0	0.0	0.1	0.0	0.1	0.1	0.0
18	P108	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.1
19	W028	1.0	1.1	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.0
20	C219	1.0	0.0	1.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
Mean		***0.77***	***0.81***	***0.38***	***0.26***	***0.06***	***0.04***	***0.11***	***0.04***	***0.18***	***0.03***
Std Dev		***0.76***	***0.72***	***0.59***	***0.56***	***0.05***	***0.05***	***0.23***	***0.05***	***0.46***	***0.05***
Paired T-Test		***0.7741***		***0.1384***		***0.3605***		***0.3230***		***0.1940***	

SELF-ASSESSMENT OF ITCHING
(Scale: 0 = None to 3 = Severe)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7		Day 43 Reg 14		Day 50 Reg 21	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1
2	G227												
3	C340	0.1	0.0	0.1	0.0	1.1	1.0	0.1	0.0	0.1	0.0	0.1	0.0
4	M025	1.0	2.0	1.0	2.0	1.0	2.0	1.0	2.0	1.0	1.1	1.0	1.1
5	M691	0.1	0.0	0.1	0.0			0.1	0.0	0.1	0.0	0.1	0.0
6	T042	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.1
7	G114	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
8	J004												
9	K048	0.1	0.0	0.1	0.0			0.1	0.0	0.1	0.0	0.1	0.0
10	D017	0.1	0.0	0.0	0.1			0.0	0.1	0.0	0.1	0.0	0.1
11	N076	1.0	1.1	0.1	0.0			0.1	0.0	0.1	0.0	0.1	0.0
12	C294	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1
13	H176	1.0	1.1	1.1	1.0			2.1	2.0	3.1	3.0	0.0	1.0
14	S279	0.0	0.1	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
15	E009	1.0	0.0	2.0	0.0	2.0	0.0	1.0	0.0	0.1	0.0	0.1	0.0
16	F010	0.1	0.0	0.0	0.1					0.0	0.1	0.1	0.0
17	D283	0.0	0.1	0.0	0.1	0.0	0.1	1.1	1.0	0.0	0.1	1.0	2.0
18	P108	0.0	0.1	0.1	0.0	0.1	0.0	0.0	0.1	0.1	0.0	0.1	0.0
19	W028	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.1
20	C219	0.0	0.1	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
Mean		***0.27***	***0.27***	***0.28***	***0.19***			***0.36***	***0.32***	***0.29***	***0.26***	***0.17***	***0.26***
Std Dev		***0.41***	***0.55***	***0.53***	***0.51***			***0.59***	***0.68***	***0.74***	***0.73***	***0.31***	***0.55***
Paired T-Test		***1.0000***		***0.4970***				***0.6473***		***0.1631***		***0.2889***	

SELF-ASSESSMENT OF BURNING/STINGING
(Scale: 0 = None to 3 = Severe)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1
2	G227										
3	C340	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
4	M025	0.1	0.0	0.1	0.0	0.0	0.1	0.1	0.0	1.0	1.1
5	M691	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.1	0.0
6	T042	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
7	G114	0.1	0.0	0.1	0.0	0.0	2.0	0.1	0.0	0.1	0.0
8	J004										
9	K048	0.0	0.1	0.0	0.1	0.1	0.0	0.1	0.0	0.1	0.0
10	D017	0.1	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.0
11	N076	0.1	0.0	0.1	0.0	0.0	0.1	0.1	0.0	0.1	0.0
12	C294	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1
13	H176	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.1	0.0	0.1
14	S279	0.0	0.1	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
15	E009	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
16	F010	0.1	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.1	0.0
17	D283	0.1	0.0	0.1	0.0	0.0	0.1	0.0	0.1	0.1	0.0
18	P108	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
19	W028	0.0	0.1	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.0
20	C219	0.1	0.0	0.1	0.0	0.1	0.0	0.0	1.0	0.1	0.0
Mean		***0.07***	***0.03***	***0.06***	***0.04***	***0.06***	***0.15***	***0.05***	***0.10***	***0.13***	***0.08***
Std Dev		***0.05***	***0.05***	***0.05***	***0.05***	***0.05***	***0.46***	***0.05***	***0.23***	***0.22***	***0.26***
Paired T-Test		***0.1631***		***0.3605***		***0.4208***		***0.4210***		***0.0135***	

SELF-ASSESSMENT OF BURNING/STINGING
(Scale: 0 = None to 3 = Severe)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7		Day 43 Reg 14		Day 50 Reg 21	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1
2	G227												
3	C340	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
4	M025	0.0	1.0	1.0	2.0	1.0	1.1	1.0	2.0	1.0	1.1	1.0	1.1
5	M691	0.1	0.0	0.1	0.0			0.1	0.0	0.1	0.0	0.1	0.0
6	T042	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.1
7	G114	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
8	J004												
9	K048	0.1	0.0	0.1	0.0			0.1	0.0	0.1	0.0	0.1	0.0
10	D017	0.1	0.0	0.0	0.1			0.0	0.1	0.0	0.1	0.0	0.1
11	N076	1.0	1.1	0.1	0.0			0.1	0.0	0.1	0.0	0.1	0.0
12	C294	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1
13	H176	0.0	0.1	0.1	0.0			0.1	0.0	0.1	0.0	0.0	0.1
14	S279	0.0	0.1	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
15	E009	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
16	F010	0.1	0.0	0.0	0.1					0.0	0.1	0.1	0.0
17	D283	0.1	0.0	0.0	0.1	0.0	0.1	0.1	0.0	0.0	0.1	0.0	0.1
18	P108	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.1	0.1	0.0	0.1	0.0
19	W028	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.1
20	C219	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
Mean		***0.12***	***0.14***	***0.12***	***0.14***			***0.13***	***0.14***	***0.12***	***0.09***	***0.11***	***0.10***
Std Dev		***0.22***	***0.33***	***0.22***	***0.47***			***0.23***	***0.48***	***0.22***	***0.26***	***0.23***	***0.25***
Paired T-Test		***0.7903***		***0.7903***				***0.8592***		***0.1631***		***0.6507***	

Appendix P

Skicon-200 Conductance Data

IBS SKICON-200 CONDUCTANCE METER
(MEASUREMENT TECHNOLOGIES PROBE)

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	N/A	N/A	104.8	93.6	71.6	86.0	122.4	45.4	82.4	71.2
2	G227										
3	C340	N/A	N/A	55.8	64.4	68.2	44.4	63.6	47.6	65.8	81.2
4	M025	N/A	N/A	138.0	137.6	76.8	70.4	161.0	154.8	150.8	84.2
5	M691	N/A	N/A	36.8	37.8	27.6	33.4	51.4	42.0	53.6	64.4
6	T042	N/A	N/A	54.4	52.4	60.4	39.8	73.4	62.0	79.0	47.4
7	G114	N/A	N/A	54.8	49.0	54.4	71.2	83.6	69.2	102.6	51.4
8	J004										
9	K048	N/A	N/A	67.8	57.6	56.0	24.2	86.0	57.4	74.2	64.4
10	D017	N/A	N/A	118.6	125.8	85.0	100.4	158.2	125.6	137.2	153.8
11	N076	N/A	N/A	73.0	69.4	46.8	67.8	92.6	123.4	89.0	107.2
12	C294	N/A	N/A	53.8	45.8	65.2	48.8	66.8	46.2	75.0	59.4
13	H176	N/A	N/A	46.2	59.0	61.0	45.6	84.0	67.0	70.8	101.4
14	S279	N/A	N/A	82.0	88.4	73.4	67.4	100.0	84.2	105.6	77.8
15	E009	N/A	N/A	121.6	111.0	92.6	133.4	141.6	106.6	161.4	127.4
16	F010	N/A	N/A	82.4	89.2	77.8	91.0	130.2	118.2	132.2	127.8
17	D283	N/A	N/A	97.2	116.0	105.4	99.4	132.6	129.2	141.8	60.8
18	P108	N/A	N/A	104.4	102.8	115.0	103.6	165.6	159.2	123.4	142.2
19	W028	N/A	N/A	104.6	96.2	85.8	75.4	110.0	106.6	108.2	135.0
20	C219	N/A	N/A	103.0	115.4	56.2	78.8	116.4	106.6	118.6	112.4
Mean				***83.29***	***83.97***	***71.07***	***71.17***	***107.74***	***91.73***	***103.98***	***92.74***
Std Dev				***29.51***	***30.42***	***21.05***	***28.47***	***35.30***	***38.60***	***32.15***	***33.83***
Paired T-Test				***0.7557***		***0.9828***		***0.0046***		***0.1587***	

IBS SKICON-200 CONDUCTANCE METER
(MEASUREMENT TECHNOLOGIES PROBE)

		Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	77.0	72.0	79.8	71.8	70.0	77.2	70.2	59.6
2	G227								
3	C340	53.4	49.2	38.4	49.2	62.0	71.4	62.6	58.8
4	M025	189.0	105.8	97.8	124.6	141.2	144.0	129.8	77.0
5	M691	42.6	95.8	35.8	78.2			29.8	26.2
6	T042	73.2	53.8	82.8	61.0	63.0	48.0	51.8	42.4
7	G114	104.6	72.6	81.4	58.6	68.4	53.8	77.8	66.0
8	J004								
9	K048	94.0	55.0	59.2	47.8			53.8	51.2
10	D017	104.6	109.0	66.4	82.8			96.4	84.6
11	N076	60.6	106.8	60.8	71.6			105.6	69.6
12	C294	75.0	42.6	56.6	51.0	59.6	47.0	60.0	49.4
13	H176	45.6	59.0	82.0	56.0			51.0	74.8
14	S279	71.2	69.4	80.4	83.8	80.6	108.0	105.2	87.4
15	E009	112.6	69.0	106.2	87.6	119.0	148.0	95.2	82.2
16	F010	149.4	91.6	47.8	49.0				
17	D283	125.4	73.2	91.8	89.6	103.4	94.6	113.2	89.0
18	P108	101.2	159.4	81.2	70.6	84.6	102.8	81.6	114.6
19	W028	108.6	106.6	91.6	93.6	104.8	111.6	58.8	87.6
20	C219	117.8	80.2	95.4	41.4	82.2	89.2	143.4	78.4
Mean		***94.77***	***81.72***	***74.19***	***70.46***			***81.54***	***70.52***
Std Dev		***37.43***	***28.76***	***20.55***	***21.16***			***31.07***	***21.17***
Paired T-Test		***0.1736***		***0.4769***				***0.0940***	

Appendix Q

Water Loss Data

DERMALAB WATER LOSS PROBE

		Day -7		Day 1		Day 8		Day 15		Day 22	
#	Code	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	N/A	N/A	4.3	3.6	3.4	3.2	3.8	4.9	4.1	4.4
2	G227										
3	C340	N/A	N/A	4.4	5.4	4.4	5.2	4.3	5.8	5.5	5.9
4	M025	N/A	N/A	3.9	4.7	4.7	6.9	5.1	8.3	4.8	7.0
5	M691	N/A	N/A	4.5	4.0	4.5	6.9	4.4	7.8	4.7	9.1
6	T042	N/A	N/A	4.7	5.2	5.0	5.3	5.5	7.9	6.0	8.4
7	G114	N/A	N/A	3.9	4.3	4.5	5.7	4.7	6.6	4.2	6.4
8	J004										
9	K048	N/A	N/A	4.4	4.8	4.4	4.6	4.6	5.6	6.4	6.6
10	D017	N/A	N/A	7.7	8.0	6.5	6.2	7.0	8.1	7.2	9.3
11	N076	N/A	N/A	4.1	3.8	3.8	4.9	5.1	6.9	7.0	6.9
12	C294	N/A	N/A	5.0	5.7	6.1	6.8	6.7	8.3	7.0	7.8
13	H176	N/A	N/A	2.7	3.7	3.6	4.8	3.5	4.3	3.4	4.5
14	S279	N/A	N/A	4.3	3.8	3.6	3.8	3.8	4.2	3.7	4.2
15	E009	N/A	N/A	5.2	5.4	5.7	6.8	8.2	8.9	7.0	8.3
16	F010	N/A	N/A	6.4	6.0	5.7	6.3	8.0	7.4	7.0	7.4
17	D283	N/A	N/A	6.7	5.0	6.0	6.5	7.2	7.7	6.5	7.1
18	P108	N/A	N/A	5.2	6.4	6.5	8.1	7.5	8.9	6.5	8.4
19	W028	N/A	N/A	4.9	5.5	6.9	6.9	6.3	7.6	7.0	6.6
20	C219	N/A	N/A	4.0	4.0	4.1	5.8	4.2	5.8	5.0	5.9
Mean				***4.79***	***4.96***	***4.97***	***5.81***	***5.57***	***6.95***	***5.72***	***6.90***
Std Dev				***1.15***	***1.13***	***1.11***	***1.26***	***1.54***	***1.50***	***1.31***	***1.54***
Paired T-Test				***0.3337***		***0.0003***		***0.0000***		***0.0006***	

SORTED DATA

KGL #5305

DERMALAB WATER LOSS PROBE

#	Code	Day 29 Reg 0		Day 31 Reg 2		Day 33 Reg 4		Day 36 Reg 7	
		No Rx	Rx	No Rx	Rx	No Rx	Rx	No Rx	Rx
1	R157	4.3	4.1	3.8	4.1	4.8	5.2	5.6	6.1
2	G227								
3	C340	4.8	7.4	5.7	7.7	7.2	7.4	7.2	7.8
4	M025	4.8	7.0	6.3	6.8	5.4	6.7	6.0	7.2
5	M691	5.1	9.9	5.5	9.9			6.4	9.6
6	T042	5.9	8.1	6.5	10.8	5.8	7.5	6.1	6.8
7	G114	4.2	6.3	5.1	8.4	4.0	7.4	5.1	7.4
8	J004								
9	K048	5.3	6.1	5.4	6.9			5.3	6.6
10	D017	8.9	9.4	9.4	10.9			11.6	10.0
11	N076	3.7	6.3	5.3	7.1			5.4	6.8
12	C294	6.4	8.2	8.1	10.3	8.3	9.8	8.2	10.2
13	H176	3.3	5.3	4.1	6.1			4.8	6.3
14	S279	4.5	5.1	5.1	6.6	5.4	6.1	6.6	6.6
15	E009	6.8	8.5	7.1	10.8	7.6	10.2	10.4	12.4
16	F010	7.5	7.5	8.3	8.5				
17	D283	6.1	8.1	7.3	9.2	5.2	8.5	7.6	9.7
18	P108	5.4	7.6	6.8	7.7	5.4	8.7	7.0	9.9
19	W028	6.5	7.4	6.3	9.1	6.8	7.2	8.7	8.6
20	C219	5.2	6.9	7.0	6.6	7.4	7.8	9.1	10.8
Mean		***5.48***	***7.18***	***6.28***	***8.20***			***7.12***	***8.40***
Std Dev		***1.40***	***1.47***	***1.46***	***1.91***			***1.93***	***1.89***
Paired T-Test		***0.0000***		***0.0000***				***0.0005***	