Research Report S09-18

Confidential Material

4-DAY HAND STUDY PILOT TO DETERMINE THE POTENTIAL BENEFITS OF TOPICAL CGP FORMULATIONS ON CHAPPED HANDS

Sponsor: AkPharma, Inc.
6840 Old Egg Harbor Road
Pleasantville, NJ 08232
Alan Kligerman
Telephone: (609) 645-5100

Respectfully submitted by:

Gary Lee Grove, Ph.D. — Date: 2 APR 2009
Principal Investigator

Charles Zerweck, Ph.D. — Date: 2 Apr 2009
Director of Clinical Studies

Danielle Fendrick — Date: 2 Apr 2009
Director of Operations

cyberDERM CLINICAL STUDIES

Lawrence Park Industrial Park
700 Parkway Drive
Broomall, PA 19008

Phone: 610-325-0112 Fax: 610-325-0881

TABLE OF CONTENTS

I. OBJECTIVE 3
II. EXPERIMENTAL DESIGN 3
A. General Considerations 3
B. Panelist Selection 3
1. Inclusion Criteria 3
2. Exclusion Criteria 4
C. Treatments & Procedures 5
1. Expert Grader Evaluations 5
2. Digital Photography 6
3. Self-Assessments 6
4. Test Products and Treatment Procedures 7
D. Adverse Events 7
E. Statistical Analyses 9
III. RESULTS 10
A. Panelist Accountability 10
B. Expert Grader Assessments 10
IV. CONCLUSIONS 11
V. PROPRIETARY REPORT AND NON-ENDORSEMENT POLICY 11
VI. RECORD RETENTION 11
Appendix A: Calendar of Events 12
Appendix B: Sample Consent Form 14
Appendix C: Self Assessment Questionnaire 18
Appendix D: Randomization Schedule 19
Appendix E: Demographic Data 20
Appendix F: Expert Grader Assessments 21

I. OBJECTIVE

The objective of this study was to determine the visual and tactile effects of different topically applied test formulations containing (CGP) on dry, chapped hands.

II. EXPERIMENTAL DESIGN

A. General Considerations

This study was conducted under the supervision of Gary Grove, Ph.D. and Charles Zerweck, Ph.D., at cyberDERM Clinical Studies in Broomall, Pennsylvania. A copy of each of their curriculum vitae is on file with the Sponsor.

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

This study was conducted on a group of 17 panelists February 20-23, 2009. A calendar of events outlining the schedule of treatments and evaluative procedures that were followed during this trial is attached as **Appendix A**.

B. Panelist Selection

Approximately seventeen volunteers were recruited in order to finish with 17 panelists. Candidates were recruited from a pool of otherwise healthy suburban women who met the inclusion/exclusion criteria and were known to currently exhibit a dry chapped hand condition. Each candidate was interviewed to make certain that they had no medical problems and were not using concomitant medications that might interfere with the study results. They were also screened to make sure that they had no known allergies to soaps, fragrances, cosmetics or latex. Women who are either pregnant or breast-feeding were excluded from participating in this study. The inclusion/exclusion criteria were as follows:

1. Inclusion Criteria

a. Caucasian female between the ages of 18 and 55 with a Fitzpatrick Skin Type of I, II or III
b. Has mild to moderate visual dryness on the hands (grade of 2-6 on a 0-8 scale) as determined by an Expert Grader.

c. During participation in the study, subject agrees not to use any hand wash products on their hands other than what has been provided for in this study.
d. Agrees not to use any topically applied products to their hands such as moisturizers, lotions, creams or oils for the 3 days prior to the study and for the duration of the study.
e. Agrees to be and appears to be compliant with requirements of the study.
f. Is able to read, understand and sign the consent form.

2. Exclusion Criteria

a. Is pregnant, nursing or planning a pregnancy, as determined by interview.
b. Has a history of psoriasis,
c. Has known allergies or sensitivities to soaps, fragrances, cosmetics or latex.
d. Has any other skin condition that may be adversely affected by this study.
e. Any other condition or factor the Investigator or his duly assigned representative believes may affect the skin response or the interpretation of the test results, including but not limited to recent history of adult skin disease and self-reported pregnancy or lactation.

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

Upon being selected into the study, the panelists were reminded of the general nature and purpose of the study and were also instructed not to apply any other products nor tamper with their hands in any way during the remaining study period.

<u>During the study, the following restrictions were imposed</u>:

- Panelists must not have any marks, scars, scratches, etc. on the hands that would interfere with study related assessments.
- Panelists must refrain from swimming and using hot tubs.
- Panelists must refrain from tanning (excessive sun exposure) or using tanning beds.
- Panelists must have no known allergies or sensitivities to soaps, fragrances, cosmetics or latex.
- Panelists must be willing to not use any non study related topically applied products to their hands such as moisturizers, lotions, creams or oils for the duration of the study.

C. Treatments & Procedures

The selected panelists reported to the test facility and their arrivals were staggered. Assignment of panelist number was in order of their arrival at cyberDERM Clinical Studies.

1. Expert Grader Evaluations

Charles Zerweck, Ph.D. served as the Expert Grader for this study. In addition to selecting the final panel, he assessed the back of the hands for the amount of visual dryness/scaling, erythema, roughness/smoothness and overall skin appearance/condition on Day 1 prior to the first application and on Day 4. The data for each session was manually recorded by the Expert Grader on a worksheet. The Expert Grader was not permitted to review prior grades that he had given.

The following grading scales were used:

Visual Dryness/Scaling

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

Erythema

Grade	Description
0	None
2	Mild erythema
4	Moderate confluent erythema
6	Marked erythema with some edema
8	Marked erythema, edema, possible erosion

Roughness/Smoothness

Grade	Description
0	Normal—Smooth, soft, supple (yielding without wrinkling), resilient
2	Mild Roughness—papery/parchment like feel; slight wrinkling upon manipulation
4	Moderate Roughness—Slight sandy/grainy feel; skin wrinkles upon manipulation
6	Marked Roughness—Coarse, rigid feel; somewhat brittle
8	Severe Roughness—Rough feel, brittle; inflexible upon manipulation

Overall Skin Condition:

The scale below was used during the study:

11 point scale where 0 = Excellent, and 10 = Poor

Intermediate grades were allowed so that finer distinctions could be made. Ties were broken by forcing the Expert Grader to add 0.1 to that site which he though might be worse, except at Baseline. To maintain the Expert Grader's blindness to products, visual assessments were conducted in a separate area.

2. Digital Photography

Standardized images of the left and right hands were captured by Charles Zerweck, Ph.D., using a Canon EOS 20D digital camera with a 90 mm macro lens. Images were taken on Day 1 prior to the first application and on Day 4.

This camera apparatus was configured by Faraghan Medical Camera systems. The design incorporates a pair of Twin Lite MT 24 EX strobes at fixed positions and inclinations. The focal distance is fixed using a "stand-off" device to which the camera and strobes are mounted.

All images were reviewed, stored and retrieved using Canon Utilities Zoom Browser EX software.

3. Self-Assessments

Prior to being dispensed their designated test product; the panelists were informed that they would be asked to complete an open-ended self-assessment **(Appendix C)** at the end of the study on Day 4. The panelists were asked to take note of any product related benefits, and/or changes in skin condition aesthetics or sensation. Mrs. Sue Shea supervised as the panelists completed the open-ended questionnaire on Day 4.

4. Test Products and Treatment Procedures

Panelists were instructed to not use any topically applied products on their hands such as moisturizers, lotions, creams, or oils for the duration of the study.

Three test formulations utilized in this study were provided by the Sponsor and labeled:

Rx A Topical formulation # 091306A (control # 02-19-09) Cellerity DM
Rx B Topical formulation # 070605B (control # 02-10-09) Cellerity
Rx C Topical formulation # 020509A (control # 02-05-09) Cellerity OL

The randomization was designed, with 6 Panelists using Rx A, 6 Panelists using Rx B and 5 Panelists using Rx C, They were randomly assigned to one of the three test products (**Appendix D**).

The panelists reported to Ms. Jen Damia who served as the treatment technician. The panelists were supplied with their designated test product and were instructed to apply the test product to both hands as often as desired. Amount of product was ad lib. The panelists were provided with a copy of the treatment instructions and a diary to record the day and time of each application. Panelists treated both hands for three days, with the last treatment being on Day 3 in the evening. The Expert Grader was not involved in any treatment aspects of this study so that his assessments were done in a blind fashion and recorded in the same sequence as assessed.

D. Adverse Events

All adverse experiences, whether or not considered related to the product application, were entered on a report form. In the event of an adverse event, the Sponsor was notified within 48 hours. Copies of adverse reaction reports and follow-ups will be provided to the Sponsor.

Definition

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

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

Serious Adverse Event

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

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

Reporting of SAE

The investigator / designate must report SAE to the Sponsor within 24 hours of knowledge of the event. The information must be provided by phone or fax to the Sponsor. In addition, the investigator must forward the completed AE form with relevant information to the IRB/Ethics Committee.

Non-Serious Adverse Event

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

Severity:

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

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

Probable:	Good reasons and sufficient documentation to assume causal relationship
Possible:	Causal relationship is likely and cannot be excluded.
Unlikely:	The event is most likely related to an etiology other than the trial treatment.
Unknown:	Unable to assess due to insufficient evidence, conflicting data or poor documentation.

E. Statistical Analyses

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

The digital photographs were provided to the Sponsor after the conclusion of the study.

III. RESULTS

A. Panelist Accountability

Seventeen panelists reported to the test facility for this study, all of which qualified and started the study. **Appendix E** contains a listing of the seventeen panelist's age and sex.

B. Expert Grader Assessments

The sorted Expert Grader assessments for the amount of visual dryness/scaling, erythema, roughness/smoothness and overall skin appearance/condition of the left and right hand on Day 1 prior to the first application and on Day 4 can be found in **Appendix F.** These results are separated for each of the test formulations. A summary is presented in terms of the sum of occurrences of improvement, worsening or no change for each graded parameter.

Formulation C was associated with the highest incidence of improvement in terms of Dryness, Roughness and Overall hand condition. There were no occurrences of worsening with regard to these parameters. The level of erythema was generally found to improve or remain the same.

Formulation B was also generally associated with improvements in all graded parameters. It may be noted that this formulation appeared to be associated with the highest incidence of improvement of erythema on chapped hands.

Formulation A appeared to be the least promising in that it was associated with the lowest incidence of improved skin condition with regard to any parameter. In particular, this formulation appeared to exacerbate the dry skin condition.

IV. CONCLUSIONS

Based on the Expert Grader results of this small study it seems reasonable to make the following conclusion. Product Formulations C and B appear to be more effective than Formulation A in ameliorating the condition of dry chapped hands. Of these, Formulation C appears to be the most promising.

V. PROPRIETARY REPORT AND NON-ENDORSEMENT POLICY

This research report is considered to be proprietary and confidential by cyberDERM, inc. It is not to be shared with any third party except appropriate government regulatory agencies, media broadcast standards advertising divisions, or the National Advertising Division (NAD) of the Better Business Bureau (BBB) without written consent of an officer of cyberDERM Clinical Studies or cyberDERM, inc. The name of cyberDERM, inc., cyberDERM Clinical Studies, any officer, employee or collaborating scientist are not to be used for any advertising, promotional or sales purposes without the written consent of cyberDERM, inc. or cyberDERM Clinical Studies. If there are any questions regarding this policy, please contact Dr. Gary Grove.

VI. RECORD RETENTION

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

Appendix A: Calendar of Events

cyberDERM CLINICAL STUDIES

4-DAY HAND STUDY PILOT TO DETERMINE THE TOPICAL EFFECTS OF CGP

PROCEDURES	Day 1 Visit 1 Fri. Feb 20, 2009	Day 2 (No visit) Sat. Feb. 21, 2009	Day 3 (No visit) Sun. Feb. 22, 2009	Day 4 Visit 2 Mon. Feb. 23, 2009
Expert Grader Screening/Selection	X			
Sign consent	X			
Digital photographs	X			X
Receive product & instructions	X			
Product applied at lab	X			
Product applied as desired	X	X	X	
Test product collected				X
Self-assessment (open-ended)				X

PANEL:
Up to 17 panelists will be recruited for this study. The panel will consist of females between the ages of 18 and 55 with at least moderate dry skin on the hands.

TEST SITES:
The two test sites will be located on the back of the hands. One site will be on each hand.

EXPERT GRADER ASSESSMENTS:
An Expert Grader will screen and select the panel.

DIGITAL PHOTOGRAPHY:
Digital photographs will be taken of both hands prior to treatment on Day 1 and again after three days of treatment on Day 4.

cyberDERM
CLINICAL STUDIES

4-DAY HAND STUDY PILOT TO DETERMINE THE TOPICAL EFFECTS OF CGP (continued)

TEST PRODUCTS:
The Sponsor will supply the three test products to be used in this study. Panelists will be randomly assigned to one of the three test products according to a randomization schedule.

TREATMENT PROCEDURES:
The panelists will be supplied with their designated test product and will be instructed to apply the test product to both hands as often as desired. Amount of product will be ad lib. The panelists will be provided with a copy of the treatment instructions and a diary to record the day and time of each application. Panelists will treat both hands for three days, with the last treatment being on Day 3 in the evening.

SELF-ASSESSMENTS:
Prior to being dispensed their designated test product, the panelists will be informed that they will be asked to complete an open-ended self-assessment at the end of the study on Day 4. The panelists will be asked to take note of any product aesthetics and sensations. The panelists will be provided with an open-ended questionnaire to complete on Day 4. Copies of the questionnaires will be provided to the Sponsor at the conclusion of the study.

Appendix B: Sample Consent Form

CONSENT FORM

STUDY TITLE: 4-Day Hand Study cyberDERM #S09-18

PURPOSE OF STUDY:
To determine the visual and tactile effects of different test products on dry, chapped hands.

DURATION OF STUDY:
Approximately 4 Days (2 visits)
(Duration of study may be subject to change by Sponsor/Investigator-see below*)

DESCRIPTION OF PROCEDURE:
Approximately 20-22 panelists will participate in this study.

Visit 1 (Friday):
At your first appointment, you will report to the lab and an expert grader will assess the skin condition of your hands. If accepted onto the panel, digital photographs will then be taken of your hands. You will be randomly assigned (like the flip of a coin) to one of the three test products. You will be given a test product, instructions for use and a diary to record each time you apply the product. Apply the product as directed.

Saturday & Sunday:
Apply the product as directed. Your last application will be on Sunday evening.

Visit 2 (Monday):
You will return to the lab and an expert grader will assess the skin condition of your hands. Digital images will be taken of your hands. Your test product and diary will be collected. Your participation in this study will end.

REQUIREMENTS:
Report for all scheduled appointments; apply products as directed; avoid direct sun exposure and tanning beds; skin tone must not change during the test period; should not use any other treatments, apply any other products, or otherwise tamper with the test sites.

LIST OF MATERIALS:
Three coded products, Canon EOS Digital Camera and set-up

ANTICIPATED RISKS AND POSSIBLE SIDE EFFECTS:
Although unanticipated, there may be skin irritation and/or eye irritation including, but not limited to, redness, dryness, itching, burning/stinging. As with any unforeseen incidents of irritation, there may be resultant lightening or

darkening of the skin. This is usually temporary but could persist for a long time (even permanent). Your participation in this study may involve risks that are currently unforeseeable or unknown.

BENEFITS:
There are no known direct benefits to you as a participant in this investigational study. The findings or results, however, will permit the sponsor to determine the effects of these products.

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

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

PAYMENT SCHEDULE: $___ if complete the entire study

<<<<IF YOU ARE NON-COMPLIANT WITH THE REQUIREMENTS OF THE STUDY YOU WILL BE DISMISSED.>>>>

If you decide to withdraw from the research study, you should notify the technician and/or investigator of your intention to do so and you will be compensated up to the time of withdrawal at the rate of $___ per visit.

*In the event that the study is changed by the Sponsor (for example, cancellation of study or number and/or duration of the visits), the payment schedule may be changed to reflect this alteration in study design. The subject fee will be pro-rated based on the amount of visits completed but will not be less than the rate of $__ per visit.

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

Your participation in this study is entirely voluntary. If you withdraw from the research study, you should notify the technician and/or investigator of your

intention to do so and you will be compensated up to the time of withdrawal. You can refuse to participate in the study or quit at any time without loss of any rights or benefits to which you would be entitled. If you quit or are withdrawn from the study, you will be asked to return your unused study materials or have study ending tests and procedures for your safety.

COMPENSATION FOR STUDY-RELATED INJURY:
Any questions of injuries resulting from this study should be referred to Dr. Gary Grove at cyberDERM Clinical Studies at 610-325-0112. In the case of after hour emergencies, please call Dr. Charles Zerweck at 610-627-9236 or Dr. Gary Grove at 610-358-2381 or 610-348-4152. 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 at no cost to you. If the study personnel feel it is appropriate, you will be referred to a Consulting Physician for evaluation and treatment. Medical consultation will be arranged for any subject who would like his/her responses to be evaluated by a Physician. cyberDERM has a Consulting Dermatologist available for this purpose. Study personnel will arrange to have him contact you to answer questions concerning this study and/or make an appointment for you upon request. No additional compensation is available. You will not lose any of your legal rights as a research subject by signing this consent form.

Please feel free to ask any questions regarding the study. We will not be able however; to disclose the name of the sponsoring company due to confidentiality.

CONSENT:
I hereby consent to take part in the experimental study described above under the supervision of Dr. Gary Grove and his staff. I understand that minor revisions could be made during this study, and that this will be fully explained to me, and at that time I will have the option to continue this study or withdraw. I understand that the study may involve some risks. This and my part in the study have been clearly explained and demonstrated to me and I have had complete freedom to ask any questions about the study. I understand that I am free to withdraw my consent and to discontinue my participation in this project at any time. I also certify that I have brought to the attention of the investigator any changes in health status and drug use that have occurred since my initial exam. I understand and consent to what I am to do in these studies to be performed by Dr. Grove and his assistants in properly carrying out this study. FURTHERMORE, I UNDERSTAND THAT CERTAIN PRODUCTS IN THIS STUDY ARE HIGHLY PROPRIETARY TO THE SPONSOR. THEREFORE I AGREE TO KEEP SECRET THE PRODUCTS AND ALL INFORMATION PERTAINING THERETO.

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

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

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

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

_____ _____ _____

Signature of Volunteer Printed Name of Volunteer Date

_____

Person conducting consent discussion

Appendix C: Self Assessment Questionnaire

cyberDERM CLINICAL STUDIES

cyberDERM #S09-18

4-Day Hand Study

Questionnaire

#_____ ID _____ **Date _____**

Please let us know how your hands felt using the test product and if you have any other comments about the test product you've used over these past 3 days, please write them down below:

Appendix D: Randomization Schedule

cyberDERM CLINICAL STUDIES

cyberDERM #S09-18

RANDOMIZATION SCHEDULE

Rx A = Cellerity DM # 091306A
Rx B = Cellerity # 070605B
Rx C = Cellerity OL # 020509A

#	ID	Rx
1	S185	A
2	S127	B
3	B186	C
4	S230	A
5	G004	B
6	H028	C
7	B132	A
8	G005	B
9	F066	C
10	D024	A
11	D122	B
12	W094	C
13	S096	A
14	L084	B
15	L108	C
16	S013	A
17	P069	B

Appendix E: Demographic Data

cyberDERM CLINICAL STUDIES

cyberDERM #S09-18

Demographic Data

#	ID	AGE	SEX
1	S185	41	F
2	S127	49	F
3	B186	34	F
4	S230	37	F
5	G004	53	F
6	H028	45	F
7	B132	40	F
8	G005	49	F
9	F066	44	F
10	D024	46	F
11	D122	46	F
12	W094	43	F
13	S096	34	F
14	L084	54	F
15	L108	51	F
16	S013	43	F
17	P069	46	F

Appendix F: Expert Grader Assessments

Decoded & Sorted Data **cyberDERM #S09-18**

Expert Grader Ratings

Rx A = Cellerity DM # 091306A

			Visual Dry			Erythema			Rough/Smooth			Overall		
#	ID	Hand	Pre	Post D3	Change	Pre	Post D3	Change	Pre	Post D3	Change	Pre	Post D3	Change
1	S185	Right	7.0	7.0	**0.0**	6.0	4.0	**2.0**	6.0	7.0	**-1.0**	8.0	8.0	**0.0**
1	S185	Left	4.0	6.0	**-2.0**	2.0	3.0	**-1.0**	4.0	4.0	**0.0**	5.0	7.0	**-2.0**
4	S230	Right	5.0	6.1	**-1.1**	2.0	3.0	**-1.0**	3.0	4.0	**-1.0**	6.0	7.5	**-1.5**
4	S230	Left	6.0	6.0	**0.0**	4.0	4.0	**0.0**	3.1	3.0	**0.1**	7.0	7.6	**-0.6**
7	B132	Right	6.1	6.0	**0.1**	4.0	3.0	**1.0**	6.0	6.0	**0.0**	7.5	8.0	**-0.5**
7	B132	Left	6.0	5.0	**1.0**	5.0	4.0	**1.0**	5.0	5.0	**0.0**	7.0	7.0	**0.0**
10	D024	Right	7.0	7.1	**-0.1**	4.0	6.0	**-2.0**	7.0	6.0	**1.0**	8.0	8.0	**0.0**
10	D024	Left	6.0	7.0	**-1.0**	6.0	6.1	**-0.1**	6.0	6.1	**-0.1**	9.0	8.1	**0.9**
13	S096	Right	5.0	5.0	**0.0**	3.0	1.0	**2.0**	4.0	3.0	**1.0**	6.0	6.0	**0.0**
13	S096	Left	4.0	6.0	**-2.0**	4.0	3.0	**1.0**	3.0	4.0	**-1.0**	5.0	7.0	**-2.0**
16	S013	Right	6.0	7.0	**-1.0**	4.0	6.0	**-2.0**	5.0	4.0	**1.0**	7.0	8.0	**-1.0**
16	S013	Left	6.1	6.0	**0.1**	5.0	6.1	**-1.1**	6.0	4.1	**1.9**	8.0	7.0	**1.0**
Mean			**5.7**	**6.2**	**-0.5**	**4.1**	**4.1**	**0.0**	**4.8**	**4.7**	**0.2**	**7.0**	**7.4**	**-0.5**
			Improved		**1**	**Improved**		**5**	**Improved**		**4**	**Improved**		**2**
			Same		**6**	**Same**		**2**	**Same**		**5**	**Same**		**4**
			Worsened		**5**	**Worsened**		**5**	**Worsened**		**3**	**Worsened**		**6**

Decoded & Sorted Data **cyberDERM #S09-18**

Expert Grader Ratings

Rx B = Cellerity # 070605B

			Visual Dry			Erythema			Rough/Smooth			Overall		
#	ID	Hand	Pre	Post D3	Change	Pre	Post D3	Change	Pre	Post D3	Change	Pre	Post D3	Change
2	S127	Right	4	3	**1.0**	1	2	**-1.0**	4	3	**1.0**	5	4	**1.0**
2	S127	Left	5	3.1	**1.9**	2	2.1	**-0.1**	5	4	**1.0**	6	4.5	**1.5**
5	G004	Right	4	4	**0.0**	1	0	**1.0**	5	3	**2.0**	5	5	**0.0**
5	G004	Left	4.1	3	**1.1**	3	1	**2.0**	4	2	**2.0**	5.5	5.1	**0.4**
8	G005	Right	6	4	**2.0**	4	2	**2.0**	5.1	4	**1.1**	7	5	**2.0**
8	G005	Left	5	3	**2.0**	3	1	**2.0**	5	3	**2.0**	6	4	**2.0**
1	D122	Right	6	4.1	**1.9**	2	2	**0.0**	4	3.1	**0.9**	7	5	**2.0**
1	D122	Left	6.1	4	**2.1**	4	4	**0.0**	3	3	**0.0**	7.5	5.5	**2.0**
4	L084	Right	6	6	**0.0**	2	2	**0.0**	4	4	**0.0**	7	7	**0.0**
4	L084	Left	7	7	**0.0**	6	3	**3.0**	6	5	**1.0**	9	8	**1.0**
7	P069	Right	3	6	**-3.0**	2	1	**1.0**	4	5	**-1.0**	4	7	**-3.0**
7	P069	Left	4	6.1	**-2.1**	4	3	**1.0**	5	5.1	**-0.1**	6	7.5	**-1.5**
		Mean	**5.0**	**4.4**	**0.6**	**2.8**	**1.9**	**0.9**	**4.5**	**3.7**	**0.8**	**6.3**	**5.6**	**0.6**
			Improved		**7**	**Improved**		**7**	**Improved**		**8**	**Improved**		**7**
			Same		**3**	**Same**		**4**	**Same**		**3**	**Same**		**3**
			Worsened		**2**	**Worsened**		**1**	**Worsened**		**1**	**Worsened**		**2**

Decoded & Sorted Data **cyberDERM #S09-18**

Expert Grader Ratings

Rx C = Cellerity OL # 020509A

			Visual Dry			Erythema			Rough/Smooth			Overall		
#	ID	Hand	Pre	Post D3	Change	Pre	Post D3	Change	Pre	Post D3	Change	Pre	Post D3	Change
3	B186	Right	4	4	**0.0**	3	3	**0.0**	4	3	**1.0**	5	5	**0.0**
3	B186	Left	5	4.1	**0.9**	4	2	**2.0**	4.1	3.1	**1.0**	6	5.5	**0.5**
6	H028	Right	7	6	**1.0**	7	4	**3.0**	7	6	**1.0**	9	8	**1.0**
6	H028	Left	7	5	**2.0**	6	4.1	**1.9**	5	5	**0.0**	8	7	**1.0**
9	F066	Right	4	4	**0.0**	2	2	**0.0**	4	2	**2.0**	5	5	**0.0**
9	F066	Left	5	4.1	**0.9**	3	3	**0.0**	5	3	**2.0**	6	5.1	**0.9**
12	W094	Right	6	5	**1.0**	4	4	**0.0**	5	4.1	**0.9**	7	6	**1.0**
12	W094	Left	5	3	**2.0**	2	3	**-1.0**	4	4	**0.0**	6	4	**2.0**
15	L108	Right	6.1	4	**2.1**	1	1	**0.0**	5	2	**3.0**	7	5	**2.0**
15	L108	Left	6	3	**3.0**	3	2	**1.0**	7	2.1	**4.9**	8	4	**4.0**
		Mean	**5.5**	**4.2**	**1.3**	**3.5**	**2.8**	**0.7**	**5.0**	**3.4**	**1.6**	**6.7**	**5.5**	**1.2**
			Improved		**8**	**Improved**		**4**	**Improved**		**8**	**Improved**		**7**
			Same		**2**	**Same**		**5**	**Same**		**2**	**Same**		**3**
			Worsened		**0**	**Worsened**		**1**	**Worsened**		**0**	**Worsened**		**0**

cyberDERM
CLINICAL STUDIES

Lawrence Park Industrial Park
700 Parkway Drive
Broomall, PA 19008

Certified WBENC Women's Business Enterprise

Tel: 610-325-0112
Fax: 610-325-0881
Email: cyberDERM@comcast.net

RECORD RETENTION FORM

cyberDERM #: S09-18 SPONSOR #:

STUDY TITLE: **4-DAY HAND STUDY PILOT TO DETERMINE THE POTENTIAL BENEFITS OF TOPICAL CGP FORMULATIONS ON CHAPPED HANDS**

SPONSOR: AkPharma, Inc.

ADDRESS: 6840 Old Egg Harbor Road, Pleasantville, NJ 08232

CONTACT: Alan Kligerman DATE: 2 April 2009

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

☐ I authorize the study records to be destroyed:

Printed Name of Sponsor	Signature of Sponsor	Date

☒ I request the study records to be forwarded to:

Name: AKPharma, Inc.

Address: 6840 OLD EGG HARBOR ROAD, PLEASANTVILLE, NJ 08232

Telephone: (609)645-5700

Method of Shipping: ☒ UPS (acct. #) 070861 ☐ FedEx (acct. #)

☐ Other

Printed Name of Sponsor	Signature of Sponsor	Date
Charles L. Bove		1/8/10