

Protocol GLI.04.US.SL.035

CONFIDENTIAL

Title A multi-center, open-label, in-use study to assess efficacy and tolerability of topical skincare products on psoriasis patients

Protocol number GLI.04.US.SL.035

Sponsor name and address Galderma Laboratories, L.P.
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USA

Study products Cetaphil® Gentle Skin Cleanser
Cetaphil® Moisturizing Cream
Cetaphil® Daily Facial Moisturizer SPF 35 (supporting)

Investigator agreement I have read the clinical study described herein, recognize its confidentiality, and agree to conduct the described study in compliance with Good Clinical Practices (GCP), the ethical principles contained within the Declaration of Helsinki, this protocol, and all applicable regulatory requirements.

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A MULTI-CENTER, OPEN-LABEL, IN-USE STUDY TO ASSESS EFFICACY AND TOLERABILITY OF TOPICAL SKINCARE PRODUCTS ON PSORIASIS PATIENTS

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1. SYNOPSIS

Clinical Study Title:	A multi-center, open-label, in-use study to assess efficacy and tolerability of topical skincare products on psoriasis patients
Clinical Trial Number:	GLI.04.US.SL.035
Clinical Study Phase:	Phase 4
Indication:	The study products will be applied topically.
Study population:	Adult subjects having mild-to-severe plaque psoriasis, with active target lesion plaques, and currently on or starting a prescription treatment for plaque psoriasis
Country(ies) Involved and Planned Number of Study Centers:	USA Sites: 2 sites at 3 study centers
Number of Subjects:	40-50 subjects to complete, with 20-25 subjects to complete per study site.
Clinical Study Design:	<p>This is a multi-center, open-label, in-use study.</p> <p>Subjects will report to the site at Baseline (day 0) visit, will be given an informed consent form, HIPAA form, photography release form, and medical history form to complete.</p> <p>Subjects will be screened on the basis of the selection criteria for study qualification. Eligible subjects will be assessed at Baseline visit and instructed to start applying the skincare products to the assigned side of the body based on the pre-determined randomization.</p> <p>Subjects to return to the site at Week 2 (\pm 3 days), Week 4 (\pm 5 days), and Week 8 (\pm 5 days) for follow-ups.</p>
Primary Objective	To assess efficacy and tolerability of skincare products when used in conjunction with prescription treatment for plaque psoriasis via investigator and subject assessments at follow-up visits compared to Baseline.
Secondary Objective(s)	To evaluate subject's life quality using Quality of Life (QoL) questionnaire at the end of the study compared to Baseline.

	To characterize the study treatment satisfaction using self-assessment questionnaires at each follow-up visits.
Exploratory Objective:	To assess change in skin parameters via imaging analysis at follow-up visits compared to Baseline.
Clinical Study Duration:	The planned duration of recruitment and study visit (from FSI to LSO) is approximately 5 months.
Duration of Subject Participation:	Clinical study participation for subjects is 8 weeks.
Inclusion criteria:	<p>The subjects must meet all the following criteria to be eligible for the study:</p> <ol style="list-style-type: none"> 1. Adult subjects aged 18 years and above 2. Females or males 3. Any Fitzpatrick skin types I-VI, with effort to include n = 2 for each category 4. Any races, with effort to include minimum 10% minority (n = 4) such as American Indian or Alaska Native, Eastern/Southeastern Asian, South Asians, Black or African American, Native Hawaiian <u>or</u> Other Pacific Islander. 5. Any ethnicities, with effort to include minimum 10% (n = 4) of Hispanic, Latino, or Spanish origin 6. Having active target lesion plaques, with minimum area of 2 cm x 2 cm 7. Having mild-to-severe plaque psoriasis with at least 3% Body Surface Area (BSA) and cumulative Target Lesion Severity Score (TLSS) ≥ 6. 8. Currently on or starting a plaque psoriasis prescription treatment such as biologics, oral or topical therapy for psoriasis, or UV therapy. 9. Subject in general good health 10. Subject willing to stop using current topical skincare products during the duration of the study. 11. Subject willing to replace current skincare products with study products for the duration of the study. 12. For female subjects of childbearing potential, she must not be pregnant, breastfeeding or planning pregnancy during the course of the study. Subjects must be willing to take a urine pregnancy test (UPT) at Baseline visit. <ul style="list-style-type: none"> ▪ Females of non-childbearing potential, e.g., post-menopausal (absence of menstrual bleeding for 1 year without any other

	<p>medical reason), hysterectomy, or bilateral ovariectomy, are not required to have a UPT.</p> <p>13. Ability of giving consent for participation in the study</p> <p>14. Willing to sign a photography release, with minimum 80% of total study panel</p> <p>15. Agreement to adhere to the procedures and requirements of the study and to report to the site on the day(s) and at the time(s) scheduled for the assessments</p>
Exclusion criteria:	<p>The presence of any of the following exclusion criteria excluded a subject from enrollment in the study:</p> <ol style="list-style-type: none"> 1. Pregnant, breastfeeding, or planning pregnancy during the course of the study. 2. Subjects with any known allergies or hypersensitivity to any cosmetics, personal care products, and/or fragrances. 3. History of cancer within the past 5 years 4. History or presence of any skin condition/disease, besides plaque psoriasis, that might interfere with the diagnosis or evaluation of study parameters at the discretion of the investigator. 5. Planning on having surgeries and/or invasive medical procedures during the course of the study 6. Treatment with chemotherapy, immunosuppressive agents, prescription corticosteroids for psoriasis, immunomodulatory therapy (e.g., monoclonal antibodies or antiviral treatment for human immunodeficiency virus or hepatitis C) 7. History or presence of any medical condition that, in the opinion of the Investigator, would make the subject unsuitable for inclusion (e.g., a chronic, relapsing, or hereditary disease that may interfere the outcome of the study). 8. Other condition preventing the subject from entering the study in the Investigator's opinion, (e.g., subjects failing baseline assessments, subjects not likely to avoid other treatments in the treated areas, subjects anticipated to be unavailable or incapable of understanding the study assessments or having unrealistic expectations of the treatment result). 9. Study site personnel, close relatives of the study site personnel (e.g., parents, children, siblings, or spouse), or employees and close relatives of employees at the Sponsor company. 10. Participation in any interventional clinical study within 30 days of screening or planning to participate in another interventional clinical research study while enrolled in this trial.

Investigational Products:	Cetaphil® Moisturizing Cream Cetaphil® Gentle Skin Cleanser Cetaphil® Daily Facial Moisturizer SPF 35 (supporting product)
Treatment Area / Treatment Regimen / Mode of Administration	Step 1: clean the skin with the study cleanser once daily. Step 2: with clean dry hands, apply the study moisturizing cream to the lesion areas. The study moisturizing cream will be applied at least twice daily, in tandem with prescription psoriasis treatment, following the provided instructions. Subjects may apply the test product more frequently as needed.
Effectiveness Assessments:	BSA, TLSS, and PSA grading by investigator. Standardized photography of target lesions using digital camera. Macroscopic camera with imaging analysis, and capacitance imaging system (Site 2 only). Treatment satisfaction using QoL and self-assessment questionnaire.
Safety Assessments:	Tolerability assessment by investigator and subject. Adverse Events will be obtained from signs and symptoms reported by the subject or detected during study visit.
Statistical Methods:	In general effectiveness, safety and baseline characteristics variables will be presented using descriptive statistics, and graphs as appropriate. Continuous endpoints will be summarized using descriptive statistics, e.g., mean, median, standard deviation, minimum and maximum values. Categorical endpoints will be presented in frequency tables with number and percentage of observations for each level.

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2. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

AE	Adverse Event
BSA	Body Surface Area
Childbearing Potential	A female (including pre-menopausal subjects) capable of becoming pregnant; this includes women on oral, injectable, or mechanical contraception or women whose male partners have been vasectomized or are utilizing mechanical contraceptive devices
CTA	Clinical trial agreement
CTN	Clinical trial number
CV	Curriculum vitae
EC	Ethics Committees
EOS	End of Study
FSI	First subject in, i.e., first subject who signs the informed consent form
FST	Fitzpatrick Skin Type
GCP	Good clinical practice
GDPR	General Data Protection Regulation
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IFU	Instructions for use
Investigator	The Principal Investigator (PI) or other qualified person, i.e. sub-Investigator, designated and supervised by the PI at a study site to perform critical study-related procedures or to make important study-related decisions as specified on the signature and delegation log
Investigator file	Essential documents relating to a clinical study as defined in applicable GCP guidance document and maintained by the Investigator.
ISO	International Organization for Standardization
ITT	Intention-to-treat
LSO	Last subject out
MedDRA	Medical Dictionary for Regulatory Activities
NSAID	Non-steroidal anti-inflammatory drugs
PGA	Physician Global Assessment
PI	Principal Investigator; qualified person responsible for conducting the study at a study site

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SAE	Serious Adverse Event
TLSS	Target Lesion Severity Score
Study products	The products used for treatment in under study
Study site	Institution or site where the study is carried out
Tx	Treatment
UPT	Urine pregnancy test
VAS	Visual Analogue Scale
WHO	World Health Organization

3. BACKGROUND AND RATIONALE

Psoriasis is a chronic inflammatory skin condition that affects 2% of the population worldwide, and is characterized by the formation of distinct, scaly, erythematous plaques.^{1, 2} These plaques can be painful, pruritic, and disfiguring. Psoriasis can substantially diminish quality of life and negatively affect patient's well-being.² In mild to moderate disease, first-line treatment typically involves topical therapies, such as corticosteroids, vitamin D3 analogues and combination products. Biologic agents have emerged as highly potent treatment options for moderate to severe psoriasis; however, because complete clearance is not always achieved by a biologic agent, most patients who receive biologic therapies continue to use adjunctive topical therapies³.

Skincare products in the treatment of psoriasis have historically been thought to provide only symptomatic relief, but new evidence suggests moisturizers may confer therapeutic benefit by supporting epidermal barrier repair. Patients with psoriasis are advised to moisturize using lipid-replenishing ointments or creams to relieve itching and prevent skin dryness, and as such, frequent application of moisturizers has been standard in the management of psoriasis⁴. Other researchers have noted that moisturizers can confer therapeutic effects in psoriasis⁵. One study involving Cetaphil Moisturizing Cream found that use of moisturizer alone prevented further damage to skin barrier and increased skin hydration⁶. This study is to assess the efficacy of Cetaphil skincare products when used in conjunction with prescription treatment for plaque psoriasis.

4. STUDY OBJECTIVES AND CLINICAL HYPOTHESIS

4.1 Study Objectives

The primary objective of this study is:

- To assess efficacy and tolerability of skincare products when used in conjunction with prescription treatment for plaque psoriasis via investigator and subject assessments at follow-up visits compared to Baseline.

The secondary objectives of this study are:

- To evaluate subject's life quality using Quality of Life (QoL) questionnaire at the end of the study compared to Baseline.
- To characterize the study treatment satisfaction using self-assessment questionnaires at each follow-up visits.

The exploratory objective of this study is:

- To assess change in skin parameters via imaging analysis at follow-up visits compared to Baseline.

4.2 Clinical Hypothesis

The study skincare products will produce a statistically significant decrease in psoriasis clinical grading scores over the course of 8 weeks of use when compared with baseline scores. Additionally, the study products will be well tolerated by subjects, with no statistically significant increases in scores for tolerability parameters at any study time point when compared to baseline

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scores. Furthermore, the study products will be well perceived by subjects according to analyses of QoL assessment, with a statistically significant improvement in subject response values when compared with baseline, and self-assessment questionnaire, with a statistically significant proportion of favorable responses compared to unfavorable responses.

For the explorable endpoint, the study products will produce a statistically significant improvement in efficacy via imaging analysis values over the course of the study when compare with baseline.

5. OVERALL STUDY DESIGN

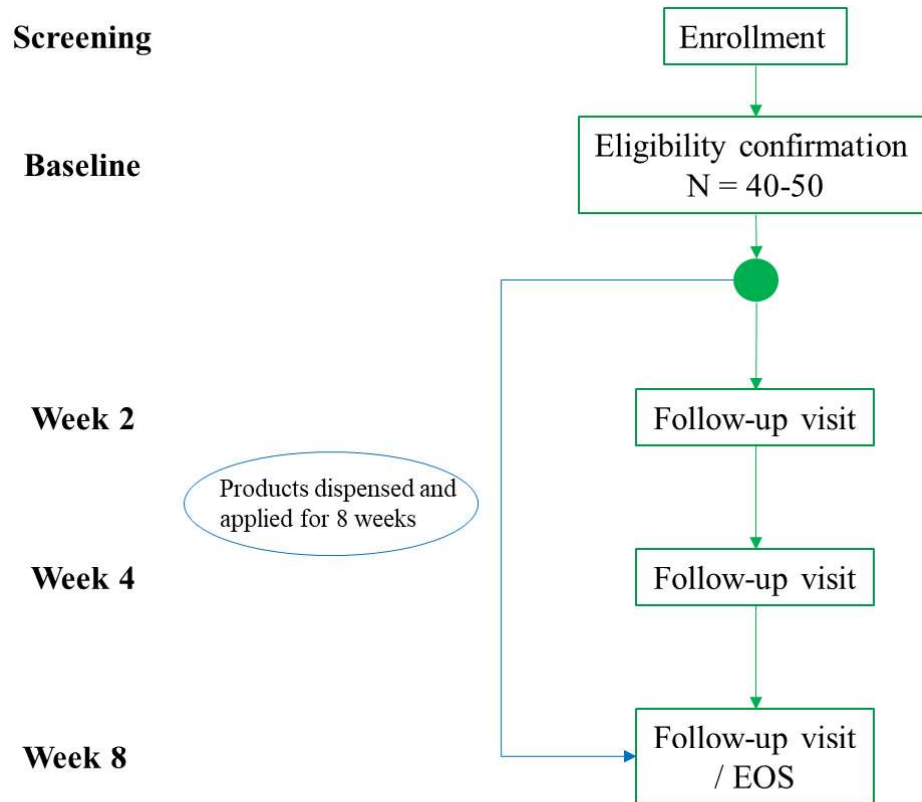
This is a multi-center, open-label, in-use study.

Subjects will report to the site at Baseline (day 0) visit, will be given an informed consent form, HIPAA form, photography release form, and medical history form to complete.

Subjects will be screened on the basis of the selection criteria for study qualification. Eligible subjects will be assessed at Baseline visit and instructed to start applying the skincare products to the assigned side of the body based on the pre-determined randomization.

Subjects to return to the site at Week 2 (± 3 days), Week 4 (± 5 days), and Week 8 (± 5 days) for follow-ups. The study flow chart is illustrated in Figure 1.

Figure 1. Study Flow Chart



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6. SELECTION AND DISPOSITION OF STUDY POPULATION

6.1 Number of Subjects

An appropriate number of subjects meeting inclusion/exclusion criteria listed below will be enrolled on the study to achieve minimum 40 (maximum 50 subjects) who complete the study as planned.

Each study site is to enroll and complete with 20-25 subjects, with 40-50 subjects expected to complete when combined.

6.2 Study Population Characteristics

Adult subjects having mild-to-severe plaque psoriasis, with active target lesion plaques, and currently on or starting new prescription treatment for plaque psoriasis.

6.3 Inclusion Criteria

The subjects must meet all the following criteria to be eligible for the study:

1. Adult subjects aged 18 years and above
2. Females or males
3. Any Fitzpatrick skin types I-VI, with effort to include $n = 2$ for each category
4. Any races, with effort to include minimum 10% minority ($n = 4$) such as American Indian or Alaska Native, Eastern/Southeastern Asian, South Asians, Black or African American, Native Hawaiian or Other Pacific Islander.
5. Any ethnicities, with effort to include minimum 10% ($n = 4$) of Hispanic, Latino, or Spanish origin
6. Having active target lesion plaques, with minimum area of 2 cm x 2 cm
7. Having mild-to-severe plaque psoriasis with at least 3% Body Surface Area (BSA) and cumulative Target Lesion Severity Score (TLSS) ≥ 6 .
8. Currently on or starting a plaque psoriasis prescription treatment such as biologics, oral or topical therapy for psoriasis, or UV therapy.
9. Subject in general good health
10. Subject willing to stop using current topical skincare products during the duration of the study.
11. Subject willing to replace current skincare products with study products for the duration of the study.
12. For female subjects of childbearing potential, she must not be pregnant, breastfeeding or planning pregnancy during the course of the study. Subjects must be willing to take a urine pregnancy test (UPT) at Baseline visit.
 - Females of non-childbearing potential, e.g., post-menopausal (absence of menstrual bleeding for 1 year without any other medical reason), hysterectomy, or bilateral ovariectomy, are not required to have a UPT.

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13. Ability of giving consent for participation in the study
14. Willing to sign a photography release, with minimum 80% of total study panel
15. Agreement to adhere to the procedures and requirements of the study and to report to the site on the day(s) and at the time(s) scheduled for the assessments.

6.4 Exclusion Criteria

The presence of any of the following exclusion criteria excluded a subject from enrollment in the study:

1. Pregnant, breastfeeding, or planning pregnancy during the course of the study.
2. Subjects with any known allergies or hypersensitivity to any cosmetics, personal care products, and/or fragrances.
3. History of cancer within the past 5 years
4. History or presence of any skin condition/disease, besides plaque psoriasis, that might interfere with the diagnosis or evaluation of study parameters at the discretion of the investigator.
5. Planning on having surgeries and/or invasive medical procedures during the course of the study
6. Treatment with chemotherapy, immunosuppressive agents, prescription corticosteroids for psoriasis, immunomodulatory therapy (e.g., monoclonal antibodies or antiviral treatment for human immunodeficiency virus or hepatitis C)
7. History or presence of any medical condition that, in the opinion of the Investigator, would make the subject unsuitable for inclusion (e.g., a chronic, relapsing, or hereditary disease that may interfere the outcome of the study).
8. Other condition preventing the subject from entering the study in the Investigator's opinion, (e.g., subjects failing baseline assessments, subjects not likely to avoid other treatments in the treated areas, subjects anticipated to be unavailable or incapable of understanding the study assessments or having unrealistic expectations of the treatment result).
9. Study site personnel, close relatives of the study site personnel (e.g., parents, children, siblings, or spouse), or employees and close relatives of employees at the Sponsor company.
10. Participation in any interventional clinical study within 30 days of screening or planning to participate in another interventional clinical research study while enrolled in this trial.

6.5 Concomitant Therapies

All treatments and therapies used 30 days prior to enrollment and all treatments or therapies used during the course of the study must be recorded in the Case Report Form (CRF) or electronic Case Report Form (eCRF).

6.5.1. Authorized Therapies

Prescription treatments for plaque psoriasis, including biologics, oral or topical therapy for psoriasis, and UV therapy, are required for this study.

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Unless listed under the exclusion criteria (see Section 6.4) or in Prohibited Therapies (see Section 6.5.2), other therapies to treat ongoing conditions are authorized.

6.5.2. Prohibited Therapies

None other than as specified in the Inclusion/Exclusion criteria.

The decision to administer a prohibited medication/treatment should be made with the safety of the subject being the primary consideration. Whenever possible, Galderma Laboratories, L.P. should be notified before the prohibited medication/treatment is administered to discuss possible alternatives.

If a subject receives prohibited therapy during the study, the subject may be allowed (at the discretion of the Investigator / Galderma Laboratories, L.P.) to continue in the study for safety evaluation purposes, only.

7. STUDY TREATMENT

The term “study treatment” refers to the study products (see Section 7.1).

7.1 Study Product Identification and Use

<i>Study product:</i> Cetaphil® Gentle Skin Cleanser	
Form	Gel
Mode of administration	Topical
How supplied	Bottle
Formula number	L2-2688A.1 (1747)
Lot number	To be added upon study completion
Storage and handling	Store at room temperate conditions: 15°C to 25°C (or 59°F to 77°F), away from sunlight

<i>Study product:</i> Cetaphil® Moisturizing Cream	
Form	Cream
Mode of administration	Topical
How supplied	Jar and bottle
Formula number	L2-2299A.1 (1765)
Lot number	To be added upon study completion
Storage and handling	Store at room temperate conditions: 15°C to 25°C (or 59°F to 77°F), away from sunlight

<i>Supporting product:</i> Cetaphil® Daily Facial Moisturizer SPF 35	
Form	Lotion

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Mode of administration	Topical
How supplied	Bottle
Formula number	217-19229-42 (1727)
Lot number	To be added upon study completion
Storage and handling	Store at room temperate conditions: 15°C to 25°C (or 59°F to 77°F), away from sunlight

The ingredient lists for the study products can be found in Appendix I.

7.2 Additional Products and Materials

The Sponsor will provide study products and supporting products to be used by subjects during the study. The Sponsor will not provide any prescription treatment for plaque psoriasis. The study overhead will cover any additional materials or supplies.

7.3 Study Product Accountability

Upon receipt of the study products, the Investigator or designee will conduct an inventory. In accordance with federal regulations, the Investigator must agree to keep all test article in a secure location with restricted access. Designated study personnel will provide the test article to the subjects in accordance with the protocol.

During the study, the Investigator must maintain records of study treatment dispensation and collection for each subject. This record must be made available to the study monitor for the purposes of verifying the accounting of clinical supplies. Any discrepancies and/or deficiencies between the observed disposition and the written account must be recorded along with an explanation. At the conclusion of the study, the Investigator will be responsible for returning all unused study products (i.e., Cetaphil® products) unless otherwise instructed by the Sponsor. Shipping label and cost will be provided to the Investigator by the Sponsor.

7.4 Study Product Preparation

All study products will be blinded and relabeled as below:

Study Product	Relabel
Cetaphil® Gentle Skin Cleanser	Product name: Cleanser Formula number: 1747 Lot number: xxx Storage conditions: 59°F - 77°F For Clinical Trial Purposes Only
Cetaphil® Moisturizing Cream	Product name: Moisturizer Formula number: 1765 Lot number: xxx Storage conditions: 59°F - 77°F For Clinical Trial Purposes Only

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Cetaphil® DFM SPF 35	Product name: Sunscreen SPF 35 Formula number: 1727 Lot number: xxx Storage conditions: 59°F - 77°F For Clinical Trial Purposes Only
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7.5 Treatment Product Dispensing

All treatment products, except the prescription treatment for psoriasis, will be administered only to subjects enrolled in the study, at no cost to subjects, and in accordance with the conditions specified in the protocol.

7.6 Treatments Compliance

Subjects will complete a daily diary, recording treatment product applications and comment during the study. Treatment products and diary will be dispensed at each study visit and reviewed for compliance at the subsequent visits. Treatment products will be visually inspected and weighed prior to distribution at each visit. If subjects do not return the treatment products and daily diary at the study visits, a verbal confirmation will be obtained for usage compliance.

Any suspected noncompliance with the treatment product or study instructions will be addressed by the Investigator or clinic staff. The Investigator will determine whether a subject's noncompliance will affect the study outcome and whether the data should be excluded from statistical analyses.

8. TREATMENT OF SUBJECTS

8.1 Informed Consent Form

An IRB-approved informed consent form (ICF) will be given to each prospective subject before participation in any study procedures. Prospective subjects will be given as much time as needed to read the ICF and will have the opportunity to have any study-related questions answered to their satisfaction prior to signing the ICF. If further questions exist, prospective subjects will be given sufficient time during the visit to have questions regarding the study and/or the ICF answered by the Investigator or study coordinator prior to signing.

8.2 Subject Identification

Enrolled subjects will be assigned a 3-digit number in conjunction with their initials that will uniquely identify every subject on the study. The numbers will remain with the subject throughout the study and should be used in all references to the individual in this study. No subject number will be reassigned once the study begins.

8.3 Subject Instructions for the Study

Subjects will be provided with the following instruction to follow during the study:

8.3.1. Study Product Usage Instructions:

The study products are used on both face and body:

- *Step 1: Cleanser* – wet skin with lukewarm water, apply the cleanser to wet skin and massage gently. Rinse well and pat dry.
- *Step 2: Moisturizer* – at least twice daily, in the morning and evening, apply the moisturizer liberally to the lesions and all over the body. Reapply the moisturizer as needed throughout the day.
 - If your psoriasis treatment is topical prescription, you can first apply the prescription treatment following its instruction. Wait at least 10 minutes before applying the study moisturizer to the lesions and all over.
- *Step 3: Sunscreen SPF 35* – if you are planning on spending time outdoors, apply the sunscreen to entire face and body before sun exposure once the moisturizers are fully absorbed.

8.3.2. Subject Instructions for Study Visits

- If your appointment time is in the morning (prior to noon), do not apply the study products until after completion of the clinic visit. If your appointment time is in the afternoon, you may apply the study products in the morning.
- You must show up to the study site with clean skin at every clinic visit.
- Please select clothing that will allow easy access for assessments at the clinic (e.g., loose-fitting clothing, shorts or skirts, rolled-up sleeves, no tights or boots or turtleneck shirts, etc.) depending on the affected areas.
- Bring the study products and daily diary with you to every clinic visit.

8.3.3. General Study Instructions

- Avoid extended periods of sun exposure and use of tanning beds and sunless tanning products for the duration of the study. Extra care should be taken to wear protective clothing, sunscreen, and accessories (such as sunglasses, hat, parasol) and avoid sun exposure from 10 AM to 3 PM.
- Do not use any topical skincare products on the assigned test areas including the affected areas (such as body wash, lotion, cream, oil, ointment), other than the provided study products, for the duration of the study.
- If the affected area is on the face, continue use of all regular brands of color cosmetics, makeup remover, and shaving products if used.
- Do not start using any new skincare or body care products other than the provided study products.

9. STUDY PROCEDURES

There will be 4 visits during the course of the study as illustrated in Table 1:

1. Visit 1 – Day 0 (screening/baseline)
2. Visit 2 – Week 2 (follow-up)
3. Visit 3 – Week 4 (follow-up)
4. Visit 4 – Week 8 (end of study or EOS)

Table 1. Study Visit and Assessments

Procedure	Visit 1	Visit 2	Visit 3	Visit 4
	D0	2 weeks after Baseline (± 3 days)	4 weeks after Baseline (± 5 days)	8 weeks after Baseline (± 5 days)
	Screening / Baseline	Follow-up	Follow-up	EOS
Informed consent	X			
Demographic	X			
Inclusion and exclusion criteria	X			
Concomitant medications	X	X	X	X
Lesion photography <ul style="list-style-type: none"> Digital photography Macroscopic imaging¹ Capacitance imaging¹ 	X	X	X	X
Investigator clinical grading	X	X	X	X
Subjective tolerability assessment	X	X	X	X
Quality of Life questionnaire	X			X
Self-assessment questionnaire		X	X	X
Adverse events reporting		X	X	X
Study products	W/D	I/W	I/W	I/W/C
Subject diaries	D	C/R/D	C/R/D	C/R

For study products and daily diaries: D=Distribute, C=Collect, R=Review, W=Weigh, and I=Inspect (visually).

¹Performed at Site 2 only (n = 20-25).

9.1 Visit Examinations

9.1.1. Visit 1 (Screening / Baseline / Day 0)

Screening and Baseline visit can be combined if subject meets eligibility criteria. The following screening assessments will be performed:

- Obtain ICF and HIPAA form prior to conducting any study specific activity.

Note: Prior to beginning of any study related activities, subjects will be informed about the purpose and nature of the study, the expected post-treatment events, and the potential risks involved with the treatments. Once subjects have completed reading, they will be interviewed to ensure their understanding of the aforementioned forms and be given the

opportunity to ask any study related questions. Subjects declining to sign any of the forms will be dismissed from the study.

- Assess eligibility: review inclusion/exclusion criteria. Subjects failing to meet criteria will be dismissed from the study.
- Record the subject's demographic information, medical history, and concomitant medications.
- Female subjects will need to perform UPT to confirm childbearing potential. The test result must be negative for study qualification.

Once the subject is deemed eligible by the Investigator, the following procedures should be completed:

- Randomize the subject based on the predetermined computer-generated randomization.
- Obtain pre-treatment digital photography of psoriasis lesions, as described in Section 10.2.1, if subject consents.
 - For Site 2 only, perform additional photography (macroscopic, capacitance) of the lesions, as described in Section 10.2.2, 10.2.3.
- Perform investigator clinical grading as described in Section 10.1.
- Perform tolerability assessment as described in Section 11.1.
- Perform QoL questionnaire as described in 10.3.1.
- Dispense study products and diary. Instruct subjects on study product application and diary completion. Remind subjects to bring the study products and diary to the next clinic visit.
- Schedule the next follow-up Visit 2 (Week 2 \pm 3 days).

9.1.2. Visit 2 (Week 2 \pm 3 days)

- Confirm the subject's concomitant medications.
- Collect, weight, and redistribute the study products.
- Collect, review, and distribute the diary.
- Interview subjects regarding any AEs that have occurred since starting study product application.
- Obtain digital photography of psoriasis lesions, as described in Section 10.2.1, if subject consents.
 - For Site 2 only, perform additional photography (macroscopic, capacitance) of the lesions, as described in Section 10.2.2, 10.2.3.
- Perform investigator clinical grading as described in Section 10.1.
- Perform tolerability assessment as described in Section 11.1.
- Perform self-assessment questionnaire as described in Section 10.3.2.
- Schedule the next follow-up Visit 3 (Week 4 \pm 5 days).

9.1.3. Visit 3 (Week 4 \pm 5 days)

- Confirm the subject's concomitant medications.
- Collect, weight, and redistribute the study products.

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- Collect, review, and distribute the diary.
- Interview subjects regarding any AEs that have occurred since the last visit.
- Obtain digital photography of psoriasis lesions, as described in Section 10.2.1, if subject consents.
 - For Site 2 only, perform additional photography (macroscopic, capacitance) of the lesions, as described in Section 10.2.2, 10.2.3.
- Perform investigator clinical grading as described in Section 10.1.
- Perform tolerability assessment as described in Section 11.1.
- Perform self-assessment questionnaire as described in Section 10.3.2.
- Schedule the next follow-up Visit 4 (Week 8 \pm 5 days).

9.1.4. Visit 4 (Week 8 \pm 5 days)

- Confirm the subject's concomitant medications.
- Collect and weight the study products.
- Collect and review the diary.
- Interview subjects regarding any AEs that have occurred since the last visit.
- Obtain digital photography of psoriasis lesions, as described in Section 10.2.1, if subject consents.
 - For Site 2 only, perform additional photography (macroscopic, capacitance) of the lesions, as described in Section 10.2.2, 10.2.3.
- Perform investigator clinical grading as described in Section 10.1.
- Perform tolerability assessment as described in Section 11.1.
- Perform QoL questionnaire as described in 10.3.1.
- Perform self-assessment questionnaire as described in Section 10.3.2.

9.2 Discontinued Subjects

Any subject is free to discontinue his/her participation in this study at any time and for whatever reason, specified or unspecified, and without prejudice.

An Investigator may decide to discontinue a subject from the study for safety reasons or when it is in the best interest of the subject. Galderma Laboratories, L.P. may also decide to prematurely terminate or suspend the study or the participation of a subject in the study. All data gathered on the subject prior to termination should be made available to Galderma Laboratories, L.P.

Criteria for the discontinuation of a subject during the study will include the following:

- Adverse Event
- Lack of Effect
- Pregnancy
- Subject Request
- Protocol Violation
- Lost to Follow-up
- Any unmanageable factor, in the Investigator's opinion, that may significantly interfere with the protocol or interpretation of results.

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The reason and date for withdrawal should be documented in the subject's source documents and CRFs. When possible, an explanatory comment should be added to further explain the reason for the withdrawal. If withdrawal of a subject occurs during a regular study visit, the CRF for that specific visit shall be completed as far as possible.

If a subject is withdrawn from the study, all data collected until the time of withdrawal will be used in the analyses. Subjects who receive study products and are withdrawn or discontinued from the study will not be replaced. For AEs still ongoing at the time of withdrawal, see Section 11.

10. EFFICACY ASSESSMENTS

The methods for collecting effectiveness data are described in this section. To minimize inter-observer variability, every effort should be made to ensure that preferably the same individual who makes the initial baseline assessments completes all corresponding follow-up evaluations.

Prior to participating in the following procedures, clinic personnel will ensure that subjects have clean test areas and have not applied any topical products. Subjects will acclimate to ambient conditions within the clinic with test areas exposed for at least 15 minutes. The designated rooms will be maintained at a temperature of 68-75 °F and the relative humidity will range from 35%-65%.

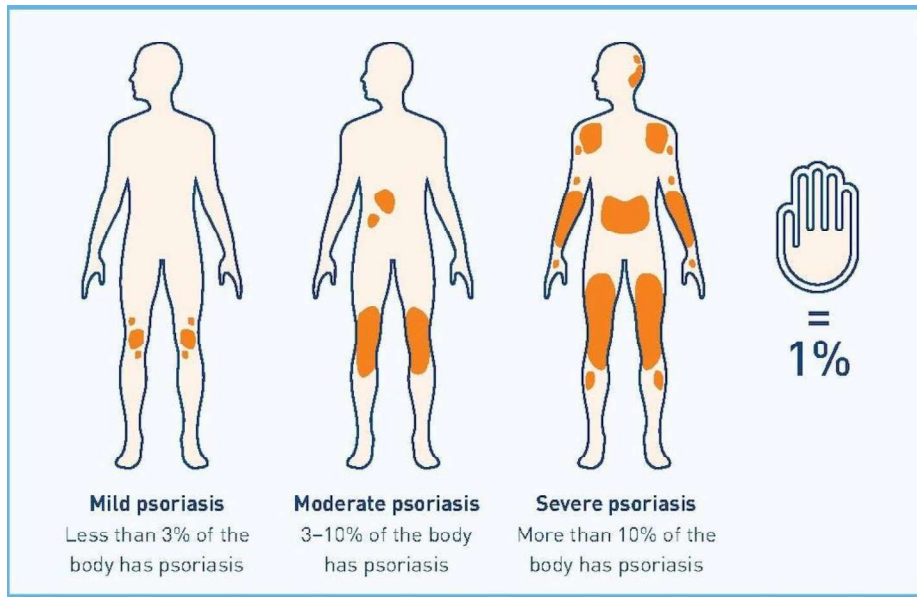
The methods for collecting efficacy data are:

- Clinical Grading by Investigator
- Lesion Photography
- Subject Questionnaire

10.1 Clinical Grading by Investigator

10.1.1. Body Surface Area (BSA)

Investigator will perform clinical grading of BSA at Baseline, Week 2, 4, and 8. BSA is a measure of how much skin is impacted by psoriasis using the following measurement.⁷ One handprint is equal approximately to 1% of BSA.

Figure 2. BSA Grading

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10.1.2. Target Lesion Severity Score (TLSS)

Investigator will perform clinical grading of TLSS, at Baseline, Week 2, 4, and 8. The target lesion parameters will be assessed using the following numerical scales.⁸ Odd scores may be used as necessary to more accurately describe the skin condition.

Table 2. TLSS Grading

Parameter	Score	Definition
Erythema	0	No evidence of erythema
	2	Pink coloration
	4	Red coloration
	6	Very red coloration
	8	Extreme red (deep red) coloration
Induration	0	No evidence of plaque above normal skin level
	2	Slight definite elevation above normal skin level
	4	Moderate elevation above normal skin level
	6	Marked elevation above normal skin level
	8	Very marked elevation above normal skin level
Scaling	0	No evidence of scaling on the lesions
	2	Mild mainly fine scales, some lesions at least partially covered
	4	Moderate somewhat coarser scale, most lesions at least partially covered
	6	Severe coarse thick scales, virtually all lesions covered with rough surface
	8	Very severe coarse very thick scales, all lesions covered with rough surface

TLSS score is calculated as cumulative total of all 3 parameters, which a maximum score of 24 (8 x 3).

10.1.3. Physician Global Assessment (PGA)

Investigator will perform clinical grading of PGA, at Baseline, Week 2, 4, and 8. The overall severity will be assessed using the following numerical scales.⁸

Table 3. PGA Grading

Score	Severity	Description
0	Clear	No signs of psoriasis (hypo/hyperpigmentation allowed). No plaque elevation. No Scaling. Erythema +/- (hyperpigmentation). Diffuse faint pink or red (macular).
1	Almost clear	Plaque elevation +/- (possible but difficult to ascertain elevation). Scaling +/- (surface dryness with some white discoloration). Erythema up to moderate (up to definite red coloration).
2	Mild	Plaque elevation slight (slight but definite, edges indistinct but sloped). Scaling fine (fine with partial or mostly covering lesions). Erythema up to moderate (up to definite red coloration).
3	Moderate	Plaque elevation moderate (moderate elevation with rough or sloped edges). Scaling coarse (coarse scale covering most or all of the lesions). Erythema moderate (definite red coloration).
4	Severe	Plaque elevation marked (marked with hard or sharp edges). Scaling coarse (coarse nontenacious scale predominates covering most of all lesions). Erythema severe (very bright red coloration).
5	Very severe	Plaque elevation very marked (very marked with hard sharp edges). Scaling very coarse (coarse thick tenacious scale covering most of all lesions with rough surface). Erythema very severe (extreme dusky to deep red coloration).

10.2 Lesion Photography

Lesion photography will be performed on subjects who consent, with minimum 80% of total study panel.

10.2.1. Digital Photography

Photographs will be taken prior to treatments with study product and at every follow-up visit in order to document treatment effect. Site personnel will be thoroughly trained in the photographic equipment and techniques before study start.

Subjects will be carefully positioned under controlled settings (e.g., room, lighting, background, etc.) to ensure standardized photography. Digital photography will be taken of the lesion per subject.

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10.2.2. Macroscopic Imaging

Macroscopic imaging procedure will be performed using Visioscan® VC 20plus at Baseline, Week 2, 4, and 8, at Site 2 only. Images will be taken of each subject's lesion at the same location.

Prior to imaging procedures, clinic personnel will ensure that subjects have clean skin on the lesion area as described in the study procedures. Subjects will be carefully positioned for each photography.

Visioscan® VC 20plus (Courage + Khazaka electronic GmbH, Koln, Germany) is a UVA-light video camera with high resolution to study the skin surface directly. The image shows the structure of the skin and the level of skin texture. The imaging area is 10 mm x 8 mm displayed in 255 pixels. The Visioscan software will be used to calculate the analyze the images for skin roughness and smoothness. Images can be displayed in 2D and 3D format.

10.2.3. Capacitance Imaging

Capacitance imaging procedure will be performed using MoistureMap MM 200 at Baseline, Week 2, 4, and 8, at Site 2 only. Images will be taken of each subject's lesion at the same location.

Prior to imaging procedures, clinic personnel will ensure that subjects have clean skin on the lesion area as described in the study procedures. Subjects will be carefully positioned for each photography.

MoistureMap MM 200 (Courage + Khazaka electronic GmbH, Koln, Germany) features a sensor based on capacitive-touch imaging technology with hardened surface. The sensor gives graphical information on the near surface hydration distribution and the micro-topography of skin and other tissue which are quantitatively assessed. The imaging area is 1.8 mm x 1.28 mm displayed on a scale of 255-pixel level, showing evenness of hydration distribution.

10.3 Subject Questionnaire

10.3.1. Quality of Life Questionnaire

Subjects will be asked about their life quality by completing a QoL questionnaire at Baseline and Week 8, as described in Appendix II.

10.3.2. Self-Assessment Questionnaire

Subjects will be asked about their perception, satisfaction, and preference with each study treatment using a self-assessment questionnaire at Week 2, 4, and 8, as described in Appendix III.

11. SAFETY ASSESSMENTS

Safety assessments for this study include:

1. Tolerability assessment

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2. An evaluation and an interview of the subjects at each follow-up visit to obtain information about any medical occurrence that meets the definition of an AE.

11.1 Tolerability Assessment

Tolerability assessment will be performed by the Investigator (dryness) and by subjects (burning/stinging and itching) using a 4-point analog scale (with half-point scores used as necessary to better describe the clinical condition). Investigator and subjects will grade the degree of irritation of target lesion areas, at Baseline, Week 2, 4, and 8.

Table 4. Tolerability Scales

Score	Grade	Description
<i>Itching: as reported by the subject within the last 24 hours</i>		
0	None	No itching
1	Mild	Slight itching, not really bothersome
2	Moderate	Definite itching that is somewhat bothersome
3	Severe	Intense itching that may interrupt daily activities and/or sleep
<i>Dryness: as assessed by the investigator</i>		
0	None	No dryness
1	Mild	Slight, but definite roughness
2	Moderate	Definite roughness
3	Severe	Marked roughness
<i>Burning/Stinging: as reported by the subject within the last 24 hours</i>		
0	None	No burning
1	Mild	Slight burning sensation; not really bothersome
2	Moderate	Definite warm, burning that is somewhat bothersome
3	Severe	Hot burning sensation that causes definite discomfort and may interrupt daily activities and/or sleep

11.2 Adverse Events

Throughout the course of the study, all adverse events will be monitored and reported on an adverse event CRF/eCRF without omitting any requested and known information. When AEs occur, the main concern is the safety of the study subjects. At time of the informed consent signature, each subject must be given the name and phone number of investigational site personnel for reporting AEs and medical emergencies.

At each visit, after the subject has had the opportunity to spontaneously mention any problems, the Investigator should inquire about AEs by asking the standard questions:

- “Have you had any health problems since your last study visit?”
- “Have there been any changes in the medicines you take since your last study visit?”

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AEs should be reported for any clinically relevant change, as determined by the Investigator, in concomitant medication(s) that is the result of an untoward (unfavorable and unintended) change from baseline in a subject's medical health following exposure to the study treatment.

Changes from baseline in any protocol-specific parameter evaluated during the study are to be reviewed by the Investigator. In addition, the subject's responses to any questionnaire utilized during the study are to be reviewed by the Investigator. Any untoward (unfavorable and unintended) change from baseline in a protocol-specific parameter or question response that is clinically relevant, in the opinion of the Investigator, is to be reported as an AE. These clinically relevant changes will be reported regardless of causality.

11.2.1. Definition of an Adverse Event

An adverse event (AE) is defined as any untoward medical occurrence in a subject taking part in the clinical study, and which does not necessarily require a causal relationship with the investigational product and/or a clinical trial procedure.

An AE can be any unfavourable and unintended sign (including an abnormal laboratory value), symptom, or disease temporally associated with the use of the investigational product, whether or not related to this product.

When an AE has a likely or very likely causal relationship with the investigational product and/or a clinical trial procedure, it is named related AE.

11.2.2. Local tolerability signs and symptoms (only applicable for cosmetic safety studies)

In cosmetic studies, local skin tolerability includes some expected functional and/or physical signs on the application area, observed by the Investigator or reported by the subjects. Those signs are collected in the final report based on scales or a diary. If the severity of a local skin tolerability sign or symptom, is such that the product application is permanently discontinued and/or a corrective concomitant treatment (except moisturizer or emollient) is prescribed, it is recorded as an undesirable effect (related AE).

11.2.3. Definition of a Serious Adverse Event (SAE) and serious undesirable effect/related SAE

A serious adverse event (SAE) means an adverse event that results in:

- i. death;
- ii. a life-threatening experience;
- iii. inpatient hospitalization;
- iv. a persistent or significant disability or incapacity;
- v. a congenital anomaly or birth defect;
- vi. an infection; or
- vii. significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of

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appearance), other than as intended, under conditions of use that are customary or usual.

Notes:

The term “immediate vital risk” refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it was more severe.

Inpatient hospitalization is considered to have occurred if the subject has had to stay for a night at the hospital. Hospitalization solely for the purpose of a diagnostic test (even if related to an AE), elective hospitalization for an intervention that was already planned before subject enrolment in the clinical trial, admission to a day-care facility, social admission (e.g., if the subject has no place to sleep), or administrative admission (e.g., for a yearly examination) should not be considered as a SAE.

A serious related SAE is defined as any SAE which the Investigator classifies as having a reasonable possibility for a causal relationship with the investigational product and/or the clinical trial procedure.

11.3 Severity Assessment

For all AEs occurring during the clinical trial, the Investigator is to classify and report the intensity of AEs using the following definitions as a guideline:

- Mild: awareness of signs and symptoms, but easily tolerated
- Moderate: discomfort, enough to cause interference with usual activity
- Severe: incapacitating, with inability to work or perform usual activity.

11.4 Causality Assessment

The Investigator is to assess the causal relationship (causality) between an adverse event and the investigational product and/or the clinical trial procedure according to the following definitions (Decision of 25 November 2013 on Guideline on Annex I to Regulation (EC) No 1223/2009 (2013/674/EU) – Causality assessment of undesirable effect caused by cosmetic products):

- Very likely
- Likely
- Unlikely
- Excluded

Medical judgment should be used to determine the relationship, considering all relevant factors including the pattern of reaction, temporal relationships, positive de-challenge or re-challenge, relevant medical history, and confounding factors such as co-medication or concurrent diseases.

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11.5 Collection, Management and Reporting Procedures

The period of collection of adverse events starts from the time of signature of the Informed Consent Form (ICF) by the subject until the end of the subject's participation in the clinical study.

If a Serious Adverse Event (SAE) is on-going at the final clinical trial visit, it should be followed by the Investigator until it has resolved or has reached a stable condition.

After the subject completes the clinical study, the Investigator should also inform the Sponsor (see Sponsor's contact details below) if he/she becomes aware of an SAE involving a subject who has participated in the clinical study.

At each post enrollment visit, the Investigator will question the subject about AEs using an open non persuasive question to elicit reporting of AEs, for example "*Have you noticed any change in your health since the last visit?*" Direct questioning and examination will be performed when appropriate.

The Investigator will obtain and maintain in the subject's files all pertinent medical records, and (if applicable) information and medical judgment from colleagues who assisted in the treatment and follow-up of the subject. If necessary, the Investigator will contact the subject's personal physician or hospital staff to obtain further details.

As a minimum, Investigators are requested to report in the Case Report Form (CRF) and in the report all related adverse events (i.e., cosmetic adverse events) and all Serious Adverse Events, whether related or not.

11.5.1. Management and reporting procedures for cosmetic adverse events (i.e., related AEs)

Cosmetic adverse events should be recorded in the CRF and summarized in the report in a summary table with at minimum the subject number, AE number, AE diagnosis or signs and symptoms, location, date of onset, seriousness, severity, action taken, relationship, date of resolution and concomitant treatment associated as well as a detailed narrative of the event.

In addition, based on his/her medical judgment, the Investigator will assess whether an cosmetic adverse events requires immediate (i.e. within 24 hours) reporting to the Sponsor. In such cases, the summary table will be sent to the Sponsor, along with the AE narrative and any other relevant information (concomitant treatments, product weighing, ...).

All cosmetic adverse events should be appropriately documented, i.e. any relevant information such as demographics, medical history and concomitant therapies should be recorded in the CRF.

The Investigator is to monitor and record the progress of the adverse effect until the last subject's study visit.

The Investigator is to update the AE narrative as appropriate, each time follow-up information is collected and when the final outcome of the adverse effect is known.

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11.5.2. Management and reporting procedures for Serious Adverse Events

The Investigator is to take the following steps:

1. Take prompt and appropriate medical action, if necessary. The safety of clinical trial subjects is the first priority.
2. Ensure the AE is classified as an SAE. Immediately inform the Sponsor's representative of the event by email (see both contact details below) and discuss further actions to be taken:

Global Vigilance email: safety.q-med@galderma.com

US Vigilance email: pharmacovigilance.USDFW@galderma.com

3. Complete the Serious Adverse Event (SAE) form provided by the Sponsor's representative **Within 24 hours**, send by e-mail **to the Sponsor's representative** the completed SAE form, accompanied any other relevant information (e.g., test results or medical records).
4. Monitor, record and send to Sponsor's representative the progress of the event until it resolves or reaches a stable outcome, with or without sequelae (send the updated SAE form with follow-up information and any other relevant information to Sponsor's representative).
5. Obtain and maintain in the subject's file all pertinent medical records, information, and medical judgments from colleagues who assisted in the treatment and follow-up of the subject. If necessary, contact the subject's personal physician or hospital staff to obtain further details.
6. If applicable, comply with the regulatory requirement(s) related to the reporting of SAEs to the Institutional Review Board (IRB) / Independent Ethics Committee (IEC).

11.6 Pregnancy

Pregnancy itself is not to be considered as an adverse event. If a pregnancy occurs during the clinical trial, **the product application should be stopped immediately**, the subject should be withdrawn from the clinical study and Sponsor's representative (see Sponsor's contact details above) should be informed **within 24 hours**.

Pregnancy must be recorded as a reason for discontinuation in the exit form of the CRF.

No specific follow-up of pregnancy is required, except if it is a regulatory requirement in the country(ies) where the clinical trial is conducted.

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12. STATISTICAL ANALYSIS

12.1 General

All study data will be listed in subject data listings.

All continuous endpoints will be summarized descriptively including N, mean, median, standard deviation, minimum and maximum values, for the observed value as well as the change from Baseline. Categorical endpoints will be presented in frequency tables with number and percentage of observations for each level.

Confidence intervals will be two-sided and constructed at a confidence level of 95%. Statistical tests will be performed at a significance level of 5%, and *p* values will be two-sided.

12.2 Analysis Population

The following populations will be defined:

Intention-to-treat (ITT)	Includes all subjects who receive the test products, i.e., at least one follow-up visit completion. Subjects are analyzed based on the as treated principle.
Per protocol (PP)	Includes all subjects in ITT who complete the study without any deviations that are considered to have substantial impact on the primary effectiveness outcome.

ITT is the primary population for all efficacy and safety analyses. The primary efficacy analysis will be repeated using the PP analysis set if there is at least a 10% difference in the number of subjects between the PP and ITT sets.

12.3 Demographics and Subject Characteristics

Demographic endpoints and subject characteristics will be presented based on the ITT analysis set using descriptive statistics, as appropriate.

12.4 Statistical Analysis Plan

Mean of the change from Baseline will be estimated at applicable post-Baseline timepoint. The null hypothesis, that the mean change from Baseline is zero, will be tested using methods described in

Table 5.

The following will be calculated and reported for each parameter at applicable post-Baseline timepoint(s):

$$\text{Percent mean change from baseline} = \frac{(\text{visit mean score} - \text{baseline mean score})}{\text{baseline mean score}} \times 100$$

$$\text{Percent of subjects improved/worsened} = \frac{(\text{number of subjects improved/worsened from baseline})}{\text{total number of subjects}} \times 100$$

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Table 5. Statistical Analysis Plan

Evaluation	Change from Baseline	Notes/Interpretation
Clinical Grading <ul style="list-style-type: none"> BSA TLSS PGA 	One-sample t-test; If normality fails, a Wilcoxon signed-rank test will be used.	A decrease in scores indicates an improvement.
Tolerability Grading <ul style="list-style-type: none"> Dryness Burning/Stinging Itching 	One-sample t-test; If normality fails, a Wilcoxon signed-rank test will be used.	A decrease in scores or lack of significant increase indicates tolerability/safety of the treatment products.
Macroscopic Imaging <ul style="list-style-type: none"> Skin smoothness Skin roughness 	One-sample t-test; If normality fails, a Wilcoxon signed-rank test will be used.	A decrease in values indicates an improvement in skin smoothness. An increase in values indicates an improvement in roughness.
Capacitance Imaging <ul style="list-style-type: none"> Homogeneity 	One-sample t-test; If normality fails, a Wilcoxon signed-rank test will be used.	An increase in values indicates a homogeneous moisture distribution.
QoL Questionnaire	Wilcoxon signed-rank test	A decrease in response values indicates an improvement.
Self-Assessment Questionnaire	N/A	Percentage of favorable and unfavorable responses will be provided for each question.

Questionnaires will be tabulated; and the frequency and percentage of all response options will be reported for each question and time point. For questionnaire inquiries without baseline response data, a binomial (sign) test will be performed to test if the proportion of the combined designated favorable responses is equal to the combined designated unfavorable responses for each applicable question. A higher percentage of favorable responses with a significant *p* value indicates positive subject perceptions of the study treatment.

A more appropriate analysis may be performed, which will be recorded in biostatistics note to file and/or in the study report.

13. ETHICAL AND REGULATORY PROCEDURES

13.1 Research Standards/Good Clinical Practice

This study will be conducted in accordance with all applicable guidelines for the protection of human subjects for research as outlined in 21 CFR 50 the accepted standards for Good Clinical Practice (GCP), and the standard practices of the study sites in accordance with the protocol and amendment(s) as applicable.

13.2 Quality Assurance/Audit/Inspection

To ensure compliance with GCP and all applicable regulatory requirements, Galderma Laboratories, L.P. may conduct a quality assurance audit of the site records, and the regulatory

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agencies may conduct a regulatory inspection at any time during or after completion of the study. The Investigator must agree to grant the auditor(s) and inspector(s) direct access to all relevant documents and to allocate their time and the time of their staff to discuss any findings/relevant issues.

13.3 Institutional Review Board

This study (protocol, ICF and all addenda) will be reviewed and approved by Sterling IRB. The study will not be activated and subjects will not be consented, receive any study products, or participate in any study procedures until the IRB has approved the protocol and the ICF. In addition, the IRB will review the study before any significant change in the protocol is initiated. After each review, the IRB's approval will be documented in a letter to the Investigator and a copy of the IRB approval letter will be forwarded to the Sponsor.

14. STUDY CONDUCT CONSIDERATIONS

14.1 Clinical Monitoring

The conduct of the study will be closely monitored by representatives of Galderma Laboratories, L.P. following GCP, ICH guidelines, applicable SOPs, guidelines, and all local regulations. The clinical investigation will be monitored to ensure that: the rights and well-being of the subjects are protected; the reported data are accurate, complete and verifiable from applicable source documents; and the study is conducted in accordance with the currently approved protocol and any other study agreements, GCP, and all applicable regulatory requirements. The Investigator will allow the Galderma Laboratories, L.P. representatives to have access to all study records, CRF/eCRF, corresponding subject medical records, and any other documents considered source documentation. The Investigator also agrees to assist the representatives, if required, which can include AE reporting.

14.2 Study Deliverables

All study data and digital images will be forwarded to the Sponsor. Images will be labeled with study number, subject number, and timepoint.

14.3 Data Collection

Investigators must keep accurate records of all subjects' visits and all procedures done, being sure to include all pertinent study related information from which CRF/eCRF data will be recorded. Data for this study may be recorded in the subject's chart (e.g., source documents / electronic records) or if approved by the Galderma Laboratories, L.P. directly into CRF/eCRFs. If electronic records are maintained, the method of verification must be determined in advance of starting the study. The process of administering the informed consent must also be documented. Any and all side effects and AEs with the concomitant therapies associated must be thoroughly documented. Results of any diagnostic tests conducted during the study should be included in the source documentation. Pertinent telephone conversations with the subjects and/or Galderma Laboratories, L.P. concerning the study will be documented and kept on file.

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It is required that the author of an entry in the source documents be identifiable. Direct access to all source documentation (medical records) must be allowed for the purpose of verifying that the data recorded in the CRF/eCRF are consistent with the original source.

Only designated individuals may complete the CRF/eCRFs. The principal Investigator will review the reported data and certify that the CRF/eCRFs are accurate and complete.

After monitoring has occurred at the clinical site(s) and the CRF/eCRFs have been reviewed, additional data clarifications and/or additions may be needed including AE reporting. Data clarifications and/or additions are documented and are part of each subject's CRF/eCRFs.

14.4 Data Management

A double-entry method will be used to enter data captured on paper records into a spreadsheet database to ensure accurate data transfer, and any missing data and/or inconsistencies will be identified and corrected.

The self-assessment questionnaire will be completed by subjects electronically using HIPAA-compliant SurveyMonkey online survey software. Paper questionnaires may be completed if needed.

All images taken from the study will be saved and shared to the Sponsor via a data-protected platform.

14.5 Record Retention

The Investigator is required to maintain up-to-date, complete regulatory documentation as indicated by Galderma Laboratories, L.P. and the Investigator's files will be reviewed as part of the ongoing study monitoring. The records must be easily accessible when needed (e.g., for a Galderma Laboratories L.P.'s audit or regulatory inspection) and must be available for review in conjunction with assessment of the facility, supporting systems, and relevant site personnel. Financial information is not subject to regulatory inspection and should be kept separately.

Galderma Laboratories, L.P. will inform the Investigator of the time period for retaining the site records in order to comply with all applicable regulatory requirements. The minimum retention time will meet the strictest standard applicable to a particular site, as dictated by local laws/regulations, Galderma Laboratories, L.P. SOPs, and/or institutional requirements.

The Investigator should take measures to prevent accidental or premature destruction of these documents. If the Investigator retires, relocates, or for other reasons withdraws from the responsibility of keeping the study records, custody must be transferred to a person who will accept the responsibility. Galderma Laboratories, L.P. must be notified in writing of the name and address of the new custodian.

14.6 Changes in Study Conduct/Amendments

No amendment will be done for modification(s) due to change in logistical or administrative aspect of the study (e.g., change in monitors, change of telephone numbers). In such a case, the appropriate institution(s) and/or person(s) will be notified of the changes.

Protocol Version 02: 29 January 2024

This document contains confidential, proprietary information.

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Modification of the protocol is prohibited without prior written agreement in the form of a protocol amendment. All amendments will be created by Galderma Laboratories, L.P. and must be approved by the IRB prior to implementation except when required to mitigate immediate safety risks or when the changes involve only logistical or administrative revisions.

Amendments may necessitate that the informed consent and other study-related material be revised. If the consent form is revised, all Subjects/subjects currently enrolled in the study may be required by the IRB to sign the approved, revised informed consent form.

14.7 Confidentiality

All the data provided to the Investigator and his/her staff and all data obtained through this Galderma Laboratories, L.P. protocol will be regarded as confidential and proprietary in nature and should not be disclosed to any third party without Galderma Laboratories, L.P.'s written consent".

15. REFERENCES

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7. National Psoriasis Foundation. (n.d.). *Why treat psoriasis?*. The National Psoriasis Foundation: National Psoriasis Foundation. <https://www.psoriasis.org/why-treat/>
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APPENDIX I: INGREDIENT LISTS

CETAPHIL® GENTLE SKIN CLEANSER

FORMULA NO: L2-2688A.1 (1747)

INGREDIENTS:

WATER
GLYCERIN
CETEARYL ALCOHOL
PANTHENOL
NIACINAMIDE
PANTOLACTONE
XANTHAN GUM
SODIUM COCOYL ISETHIONATE
SODIUM BENZOATE
CITRIC ACID

CETAPHIL® MOISTURIZING CREAM

FORMULA NO: L2-2299A.1 (1765)

INGREDIENTS:

WATER
GLYCERIN
PETROLATUM
DICAPRYLYL ETHER
DIMETHICONE
GLYCERYL STEARATE
CETYL ALCOHOL
HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL
PEG-30 STEARATE
PANTHENOL
NIACINAMIDE
PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL
TOCOPHERYL ACETATE
PANTOLACTONE
DIMETHICONOL
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER
CARBOMER
PROPYLENE GLYCOL
DISODIUM EDTA
BENZYL ALCOHOL
PHENOXYETHANOL
SODIUM HYDROXIDE
CITRIC ACID

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CETAPHIL® DAILY FACIAL MOISTURIZER SPF 35

FORMULA NO: 217-19229-42 (1727)

ACTIVE INGREDIENTS:

AVOBENZONE 2.8%
HOMOSALATE 9.5%
OCTISALATE 4.8%
OCTOCRYLENE 7.0%

INACTIVE INGREDIENTS:

WATER
GLYCERIN
DIPROPYLENE GLYCOL
PANTHENOL (VITAMIN B5)
ETHYLHEXYL METHOXYCRYLENE
ISOPROPYL PALMITATE
SILICA
NIACINAMIDE
CETEARYL OLIVATE
CETEARYL ALCOHOL
GLYCERYL STEARATE
POTASSIUM CETYL PHOSPHATE
SORBITAN OLIVATE
TOCOPHERYL ACETATE (VITAMIN E ACETATE)
CAPRYLYL GLYCOL
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER
PALMITIC ACID
ETHYLHEXYLGLYCERIN
STEARIC ACID
LEONTOPODIUM ALPINUM FLOWER/LEAF EXTRACT
1,2-HEXANEDIOL
ORYZA SATIVA (RICE) LEES EXTRACT
PROPANEDIOL
SODIUM HYDROXIDE
ADENOSINE
CITRIC ACID
MYRISTIC ACID
TOCOPHEROL (VITAMIN E)
BUDDLEJA DAVIDII (SUMMER LILAC) LEAF EXTRACT
THYMUS VULGARIS (THYME) LEAF EXTRACT

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APPENDIX II: QUALITY OF LIFE QUESTIONNAIRE

DERMATOLOGY LIFE QUALITY INDEX

DLQI

Study Site:

Date:

Score:

Subject Number:

Diagnosis:

Address:

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please check one box for each question.

1.	Over the last week, how itchy, sore, painful or stinging has your skin been?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
2.	Over the last week, how embarrassed or self conscious have you been because of your skin?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
3.	Over the last week, how much has your skin interfered with you going shopping or looking after your home or yard ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
4.	Over the last week, how much has your skin influenced the clothes you wear?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
5.	Over the last week, how much has your skin affected any social or leisure activities?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
6.	Over the last week, how much has your skin made it difficult for you to do any sport ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
7.	Over the last week, has your skin prevented you from working or studying ?	yes no	<input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
	If "No", over the last week how much has your skin been a problem at work or studying ?	A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
8.	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>

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9.	Over the last week, how much has your skin caused any sexual difficulties ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
10.	Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>

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Please check you have answered EVERY question. Thank you.

DERMATOLOGY LIFE QUALITY INDEX (DLQI) - INSTRUCTIONS FOR USE

The Dermatology Life Quality Index questionnaire is designed for use in adults, i.e. patients over the age of 16. It is self explanatory and can be simply handed to the patient who is asked to fill it in without the need for detailed explanation. It is usually completed in one or two minutes.

SCORING

The scoring of each question is as follows:

Very much	scored 3
A lot	scored 2
A little	scored 1
Not at all	scored 0
Not relevant	scored 0
Question 7, 'prevented work or studying'	scored 3

The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired.

HOW TO INTERPRET MEANING OF DLQI SCORES

0 – 1	no effect at all on patient's life
2 – 5	small effect on patient's life
6 – 10	moderate effect on patient's life
11 – 20	very large effect on patient's life
21 – 30	extremely large effect on patient's life

REFERENCES

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Basra MK, Fenech R, Gatt RM, Salek MS and Finlay AY. The Dermatology Life Quality Index 1994-2007: a comprehensive review of validation data and clinical results. *Br J Dermatol* 2008; **159**:997-1035.

Hongbo Y, Thomas CL, Harrison MA, Salek MS and Finlay AY. Translating the science of quality of life into practice: What do dermatology life quality index scores mean? *J Invest Dermatol* 2005; **125**:659-64.

There is more information about the DLQI, including over 85 translations, at www.dermatology.org.uk. The DLQI is copyright but may be used without seeking permission by clinicians for routine clinical purposes. For other purposes, please contact the copyright owners.

APPENDIX III: SELF-ASSESSMENT QUESTIONNAIRE**Week 2**

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The cleanser leaves my skin feeling clean	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The cleanser doesn't irritate my skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This cleanser doesn't dry my skin out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My skin feels nourished after using the regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
It is easy to incorporate this skincare regimen into my daily prescription routine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This moisturizer has helped the lesions feel softer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The skin lesions feel smoother since starting this moisturizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My skin looks healthier since starting this moisturizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The moisturizer keeps my skin feeling hydrated throughout the day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Week 4

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
My skin is less dry and cracked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I worry less about my skin since starting the regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
These skincare products work well with my prescription treatment as a complete regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This moisturizer helps smooth out my skin's rough texture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My skin appears healthier-looking since starting this moisturizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The skin lesions feel much softer since starting this moisturizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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This moisturizer has helped the lesions feel more hydrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The skin lesions look less flaky since starting this moisturizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Week 8

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The cleanser is gentle for daily use on my psoriasis skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My skin feels the least irritated since starting this skincare regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My skin hasn't felt this great in a long time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This is my favorite skincare regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This skincare regimen was the perfect choice as part of my prescription regimen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My skin is at the healthiest-looking state since using this moisturizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This moisturizer helps sooth my sensitive skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I love how soft my skin feels	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The skin lesions have been consistently hydrated since using this moisturizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This moisturizer helps smoothen out the rough, scaly lesions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No
I would recommend the cleanser to my family and friend	<input type="checkbox"/>	<input type="checkbox"/>
I would recommend the moisturizer to my family and friend	<input type="checkbox"/>	<input type="checkbox"/>
I would recommend the product regimen to my family and friend	<input type="checkbox"/>	<input type="checkbox"/>
I would purchase the cleanser	<input type="checkbox"/>	<input type="checkbox"/>
I would purchase the moisturizer	<input type="checkbox"/>	<input type="checkbox"/>
I would purchase the product regimen	<input type="checkbox"/>	<input type="checkbox"/>

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Testimonials (please provide any comments on your experience, study products, satisfaction/dissatisfaction, or anything related to this study)
