OMP, INC.

CLINICAL STUDY PROTOCOL

An Open-Label Study to Evaluate the Anti-Aging Effects of Three Months of Treatment using the Obagi 360 System in Subjects with Photodamage

Protocol Number: OMP360-01

Original Issue Date: 05 August 2013

Proprietary Statement:

Protocol

An Open-Label Study to Evaluate the Anti-Aging Effects of Three Months of Treatment using the Obagi 360 System in Subjects with Photodamage

Study Sponsor:	Obagi Medical Products, Inc., a Division of Valeant 3760 Kilroy Airport Way, Suite 500 Long Beach, CA 90806 Phone: 562-628-1007
Medical Monitor:	Mandeep Kaur, M.D., M.S. Executive Director, Clinical Research Medicis Pharmaceutical Corporation, a division of Valeant Phone: (480) 291-5629
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2 PROTOCOL SYNOPSIS

Study Number:	OMP360-01
Title of Study:	An Open-Label Study to Evaluate the Anti-Aging Effects of Three Months of Treatment using the Obagi 360 System in Subjects with Photodamage
Study Center(s):	Up to two study centers in the United States
Study Period:	3Q13 – 2Q14
Objectives:	To observe improvement in the appearance and the effects of the Obagi 360 skincare system when used consistently over a 3 month time period

Methodology: Open-label study of the Obagi 360 system used daily for 3 months to evaluate the effects on photodamage. Subjects will be evaluated at five time points; a baseline visit and at 2, 4, 8, and 12 weeks. The total study duration will be 12 weeks for each subject.

At the baseline visit (Day 1) the subject will complete the informed consent and photo release and will be evaluated for eligibility. Eligible subjects will be assigned a subject number and enrolled. At the baseline visit photographs will be taken and the investigator will complete the skin grading assessment. The subject will be instructed in the use of the product. The Obagi 360 skincare system will be applied once daily.

The subjects will return to clinic on Days 14 (± 2 days), and 28, 56, and 84 (± 5 days) to assess response. At each visit photographs will be obtained and the investigator will complete the skin grading assessment. Additionally, the subject will complete a self-assessment at subsequent visits.

Number of Subjects: A total of approximately 40 subjects will be enrolled

Inclusion Criteria: Subjects may participate in the study if they meet the following criteria:

1. Female subjects between the ages of 25-40
2. Fitzpatrick skin type I-IV
3. Investigator Assessment of Overall Integrated Facial Photodamage of mild to moderate (score of 2 – 5 inclusive; Section 11.1) and prone to breakouts (non-inflammatory), as assessed by the investigator.
4. Willing to withhold use of all other topical skincare products during the study with the exclusion of facial cleansers and Latisse. Make-up is allowed.
5. Willing to withhold all facial treatments during the course of the study including toxins, fillers, microdermabrasion, IPL, peels, facials, laser treatments, tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
6. Willing to remove all makeup at every visit for pictures.
7. Willing to sign Photo release.
8. Willing and able to give written informed consent.

9. Subject is able to follow study instructions, accessible for treatment and follow-up at the specified time on the specific required study visit days, and likely to complete all study requirements
10. Female subjects of child bearing potential agree to take a urine pregnancy test at the Baseline visit, end of the study and when deemed appropriate by Investigator and/or Sponsor. Subjects of childbearing potential is defined as any female who has experienced menarche and who:
    a. Has not undergone successful surgical sterilization (i.e. hysterectomy or bilateral oophorectomy)

    Or

    b. Is not post-menopausal (i.e. amenorrhea equal to or greater than 12 consecutive months)

    Or

    c. Is on hormone replacement treatment (HRT) with a documented serum follicle stimulating hormone (FSH) level of >35mIU/mL
11. Be using an acceptable method of contraception throughout the study if they are female of child-bearing potential. Acceptable methods of birth control include: oral and other systemic contraceptives, double barrier, bilateral tubal ligation, partner vasectomy and abstinence. Oral and other systemic contraceptives must be stable for three months prior to the Baseline visit. Patients on oral contraceptives agree not to alter their oral contraceptive, including dose or regimen for the duration of the study
12. No clinically significant abnormal findings based on the medical history including medication history that may affect study participation as determined by the Investigator
13. No recent history of drug or alcohol abuse.

Exclusion criteria: Subjects will be excluded from the study if they meet any of the following criteria:

1. Have known hypersensitivity to any components of the Obagi 360 products
2. Currently taking oral retinoids
3. Use of any of the following in the preceding 6 months: any laser or IPL treatment, toxin, chemical peel, dermabrasion
4. Use of any product which may cause irritation as per the judgment of the investigator
5. Use of topical retinoids in the preceding 3 months
6. Use of Alpha or Beta hydroxy acids in the preceding month
7. Significant history of eczema, atopic dermatitis, psoriasis in the facial area
8. Any active facial inflammatory condition.
9. Female subject that is pregnant, breast feeding, or planning a pregnancy during the course of the study

10. History of poor cooperation, non-compliance or unreliability
11. The Investigator deems the subject an unsuitable candidate for this study

Test product, dose and mode of administration:

Obagi 360 System consisting of: Obagi 0.5% retinol, Hydrafactor SPF30, and Exfoliating cleanser. The system will be used once daily for 3 months.

Reference therapy, dose and mode of administration:

None

Duration of treatment, enrollment and follow-up:

Duration of treatment period: 12 weeks

Criteria for evaluation:

1. Improvement in manifestations of photodamage assessed by the investigator using the Investigator's Skin Grading Assessment.
2. Assessment of improvement by the subject using the Subject's Self-Assessment.

Safety:

Safety variables include treatment-emergent adverse events (AEs), serious AEs (SAEs), treatment related AEs, and AEs leading to study discontinuation.

The investigator will assess the tolerability of the product at each visit.

Sample size:

Forty subjects will be enrolled. Forty (40) subjects are adequate to obtain information on the anti-aging effects of the Obagi 360 system.

Statistical methods:

The effect of the Obagi 360 system on photodamage will be evaluated using the Investigator's Skin Grading System. The changes from baseline in the scores will be summarized and tested for significance using the paired T-test for each time point. In addition, a summary of the distribution or scores (improvement or worsening) will be summarized and categorized as the number and proportion of subjects "Improved", "Equal to" or "Worse" than baseline. .

For the Subject's Self-Assessment, the response to each question will be summarized by the proportion of subjects in each category. No statistical testing will be performed on the Subject's Self-Assessment.

Safety will be summarized by the incidence of adverse events over the study by body system and preferred term. The tolerability will be summarized by the proportion of subjects with none, mild, moderate, and severe for each assessment by visit.

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List of Abbreviations

AE	Adverse Event
CFR	Code of Federal Regulations
CI	Confidence Interval
CRO	Contract Research Organization
CRF	Case Report Form
CV	Curriculum Vitae
EOS	End of Study
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
IEC	Independent Ethics Committee
IND	Investigational New Drug
IRB	Institutional Review Board
ITT	Intent-to-treat
MedDRA	Medical Dictionary for Regulatory Activities
OTC	Over-the-counter (drug product)
QD	Once-a-day
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
US	United States

4 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

4.1 SIGNATURE

Protocol Title:	An Open-Label Study to Evaluate the Anti-Aging Effects of Three Months of Treatment using the Obagi 360 System in Subjects with Photodamage
Protocol Number:	OMP360-01
Date:	05 August 2013
Test Product:	Obagi 360 System
Sponsor:	Obagi Medical Products, Inc, a division of Valeant

These Obagi representatives' signatures constitute approval of the protocol.

Executive Director, Clinical Research

Print Name: Mandeep Kaur, M.D., M.S.

Signature / Date:

Director, Clinical Operations

Print Name: Ron Staugaard, B.S, M.B.A

Signature / Date:

4.2 INVESTIGATOR SIGNATURE

Protocol Title:	Open Label Study to Evaluate the Anti-Aging Effects of Three Months of Treatment using the Obagi 360 System in Subjects with Photodamage
Protocol Number:	OMP-360-01
Date:	05 August 2013
Test Product:	Obagi 360 System
Sponsor:	Obagi Medical Products, Inc.

The signature of the investigator below constitutes agreement with this protocol and that the investigator will conduct this study according to all conditions of the protocol, the investigator's Clinical Trial Agreement and applicable laws and regulations, including all statements regarding confidentiality.

Investigator: _____

_____

Address: _____

_____

_____

_____

_____

Investigator Signature: _____

Date: _____

5 ETHICS

5.1 INSTITUTIONAL REVIEW BOARD (IRB)

The principal investigator will provide the IRB with all appropriate materials to permit their review and approval of the protocol. No study subject will be admitted to this study until written IRB approval of the protocol and the informed consent template has been obtained by the investigator. The investigator should file all related correspondence with the IRB. Copies of IRB approvals will be forwarded to Obagi or designee. The product for this study will not be delivered to the study site until copies of IRB approvals for the site have been supplied by the investigator to Obagi or designee.

Appropriate reports on the progress and conclusion of this study by the principal investigator must be made to the IRB at least annually in accordance with applicable government regulations. The investigator is responsible for checking what additional local reporting procedures may be applicable and complying with these requirements. Federal regulations also provide for expedited reporting of certain events to the IRB (see Section 14.2). The investigator is responsible for expedited reporting requirements that may be imposed by his or her IRB.

5.2 ETHICAL CONDUCT OF THE STUDY

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, and later revisions (insofar as such revisions are consistent with United States [US] treaty obligations and in accordance with US law), with the Common Rule (Part 46 of Title 45 of the US Code of Federal Regulations) and with Parts 50 and 56 of Title 21 of the US Code of Federal Regulations.

5.3 STUDY SUBJECT INFORMED CONSENT

The informed consent process is intended to give a study subject or patient or his or her designated representative all the information (s)he would reasonably want to know about a study, to ensure that the study subject understands the information and to give the study subject an opportunity to agree to participate in the study. A properly executed written informed consent, which has been approved by an IRB and is in compliance with 21 CFR Part 50, shall be obtained from each study subject before any study-specific procedures have been performed. The subjects must be informed about their right to withdraw from the study at any time, and that withdrawal will not affect their future medical care, treatment or benefits to which the subject is otherwise entitled. The study subject should also be informed if privacy rights under this study are exempt from the confidentiality provisions of the Health Insurance Portability and Accountability Act of 1996 pursuant to 45 CFR § 512(b)(iii) and, if so, what components of study subject confidentiality will be maintained and by whom.

The investigator shall provide a copy of the signed and dated informed consent to the study subject and will keep the original, signed form in the study subject's study file. The investigator will confirm the receipt of informed consent from each subject by a recording in the case report form (CRF).

6 BACKGROUND AND RATIONALE

6.1 BACKGROUND

Obagi products are the #1 prescription-strength, physician-dispensed skin care system in the world. The Obagi 360 System is a complete skin rejuvenation system and works on three different levels to make sure that skin gets the ultimate care, from treating skin problems to pampering the skin, and making sure that the body's largest organ functions at its best.

Obagi 360 contains: Obagi Exfoliating Cleanser, Obagi 0.5% retinol, and Hydrafactor Broad Spectrum SPF30. When used together under the guidance of a dermatologist/physician, these products are anticipated to work synergistically to provide improvement in the appearance in photodamage, fine lines, and wrinkles.

Subjects will use the Exfoliating Cleanser in the morning and evening. After use of the Exfoliating Cleanser in the morning, the Moisturizing Cream will be applied, and after use of the Exfoliating Cleanser in the evening, the Night Cream will be applied. The Exfoliating Cleanser is composed of maltodextrin (and) Eperua Falcata Bark Extract and is intended to gently exfoliate the skin in preparation for the moisturizing retinol cream. The 0.5% retinol (in both the Moisturizer and the Night Cream) is intended to improve skin texture and evens out roughness. For protection, the Hydrafactor SPF30, a physical sunblock, is used as part of the Moisturizer.

6.2 RATIONALE

The Obagi 360 System is intended for daily application. This study is designed to evaluate the effects on anti-aging when the Obagi 360 system is used daily for up to 3 months.

7 STUDY OBJECTIVE

To observe improvement in the appearance and the effects of the Obagi 360 skincare system when used consistently over a 3 month time period.

7.1 STUDY DESIGN OVERVIEW

This is an open-label study of the Obagi 360 system used daily for 3 months to evaluate the effects on photodamage. Subjects will be evaluated at five time points; a baseline visit and at 2, 4, 8, and 12 weeks. The total study duration will be 12 weeks for each subject.

At the baseline visit (Day 0) the subject will complete the informed consent and photo release and will be evaluated for eligibility. Eligible subjects will be assigned a subject number and enrolled. At the baseline visit photographs will be taken and the investigator will complete the skin grading assessment. The subject will be instructed in the use of the product. The subjects will return to clinic on Days 14, 28, 56, and 84 (± 5 days) to assess response. At each visit photographs will be obtained and the investigator will complete the skin grading assessment. Additionally, the subject will complete a self-assessment at subsequent visits.

7.2 STUDY SUBJECT ASSIGNMENT, RANDOMIZATION, AND BLINDING

This study is being conducted open-label. There is no blinding of the investigator or subject. Enrolled subjects will be assigned a sequential number at each site.

Study center(s) will be instructed to enroll approximately 30% of subjects who are prone to mild breakout (non-inflammatory).

7.3 SCHEDULE OF STUDY PROCEDURES

A table outlining the schedule of procedures for this study is presented in Table 1.

Table 1 Procedures Flow Chart

PROCEDURES	BASELINE (DAY 0)	DAY 14 (± 2 Days) and DAY, 28, 56, and 84 (± 5 Days)
	Visit 1	Visits 2 through 5
Obtain Informed Consent, HIPAA Authorization	X	
Obtain Photographic Release Form	X	
Review Inclusion/Exclusion Criteria	X	
Review Medical History	X	
Obtain Subject Demographics	X	
Conduct Investigator's Skin Grading Assessment	X	X
Urine Pregnancy Test[1]	X	X
Obtain Photographs	X	X
Conduct Subject's Self-Assessment[2]		X
Assign Subject Number	X	
Review Obagi 360 Application[3]	X	X
Dispense/Collect Obagi 360 System	X	X
Assess Tolerability		X
Review Concomitant Medications	X	X
Review Adverse Events		X
Review Compliance with Study Procedures		X

[1] UPT obtained on subjects of child bearing potential only.

[2] Subject's Self-Assessment of improvement Questionnaire (Appendix 2) will only be administered at Visit 2 and Visit 3

[3] Subjects receive instruction during visit on how to apply study treatment product. The first application of study treatment product to the face will be applied at the conclusion of the Baseline visit as part of the Study Treatment Dispensing and Application Training.

7.4 DURATION OF SUBJECT PARTICIPATION

The duration of the treatment is daily for 12 weeks. Subjects will be expected to come to the study center for the baseline visit and 4 additional study visits.

8 SELECTION OF STUDY POPULATION

8.1 INCLUSION CRITERIA

Individuals eligible for inclusion in this study must meet all the following criteria:

1. Female subjects between the ages of 25-40
2. Fitzpatrick skin type I-IV
3. Investigator Assessment of Overall Integrated Facial Photodamage of mild to moderate (score of 2 – 5 inclusive; Section 11.1) and prone to breakouts (non-inflammatory), as assessed by the investigator.
4. Willing to withhold use of all other topical skincare products during the study with the exclusion of facial cleansers and Latisse. Make-up is allowed.
5. Willing to withhold all facial treatments during the course of the study including toxins, fillers, microdermabrasion, IPL, peels, facials, laser treatments, tightening treatments. Waxing and threading is allowed but not facial laser hair removal.
6. Willing to remove all makeup at every visit for pictures.
7. Willing to sign Photo release.
8. Willing and able to give written informed consent.
9. Subject is able to follow study instructions, accessible for treatment and follow-up at the specified time on the specific required study visit days, and likely to complete all study requirements
10. Female subjects of child bearing potential agree to take a urine pregnancy test at the Baseline visit, end of the study and when deemed appropriate by Investigator and/or Sponsor. Subjects of childbearing potential is defined as any female who has experienced menarche and who:
    a. Has not undergone successful surgical sterilization (i.e. hysterectomy or bilateral oophorectomy)

    Or

    b. Is not post-menopausal (i.e. amenorrhea equal to or greater than 12 consecutive months)

    Or

    c. Is on hormone replacement treatment (HRT) with a documented serum follicle stimulating hormone (FSH) level of >35mIU/mL

11. Be using an acceptable method of contraception throughout the study if they are female of child-bearing potential. Acceptable methods of birth control include: oral and other systemic contraceptives, double barrier, bilateral tubal ligation, partner vasectomy and abstinence. Oral and other systemic contraceptives must be stable for three months prior to the Baseline visit. Patients on oral contraceptives agree not to alter their oral contraceptive, including dose or regimen for the duration of the study
12. No clinically significant abnormal findings based on the medical history including medication history that may affect study participation as determined by the Investigator
13. No recent history of drug or alcohol abuse

8.2 EXCLUSION CRITERIA

The presence of any of the following will exclude the potential study participant from entry into the study:

1. Known hypersensitivity to any components of the Obagi 360 products.
2. Currently taking oral retinoids.
3. Use of any of the following in the preceding 6 months: any laser or IPL treatment, toxin, chemical peel, dermabrasion.
4. Use of any product which may cause irritation as per the judgment of the investigator
5. Use of topical retinoids in the preceding 3 months.
6. Use of Alpha or Beta hydroxy acids in the preceding month.
7. Significant history of eczema, atopic dermatitis, psoriasis in the facial area.
8. Any active facial inflammatory condition.
9. Female subject that is pregnant, breast feeding, or planning a pregnancy during the course of the study
10. History of poor cooperation, non-compliance or unreliability
11. The Investigator deems the subject an unsuitable candidate for this study

8.3 STUDY SITES/SOURCE OF STUDY SUBJECTS

A sufficient number of subjects will be screened in order to enroll 40 subjects to the study. Up to two centers in the United States will be involved in the study. Enrollment will be stopped at all centers when the enrollment goal of 40 subjects has been reached.

8.4 STUDY SUBJECT IDENTIFICATION

Study subjects will be identified by a 3-digit site number (YYY) and a 3-digit subject number (XXX) as follows: YYY-XXX. Subject initials will be recorded as well (AAA). If the subject

does not have a middle initial, a hyphen will be used as a substitute (e.g., A-A). Subject confidentiality will be maintained by use of this method of study subject identification.

8.5 STUDY SUBJECT WITHDRAWAL OR EARLY TERMINATION

8.5.1 WITHDRAWAL/EARLY TERMINATION

An early termination occurs when an enrolled subject ceases participation in the study, prior to completing the protocol. Subjects must be permitted to withdraw from the study at any time for any reason. Subjects may be withdrawn at any time at the discretion of the investigator or sponsor for safety, compliance, or other reasons. In general, subjects should not be withdrawn by investigators prior to completion of the study unless there is documentation of any of the following:

- The investigator believes that the subject has experienced significant or disabling treatment-related adverse events (AEs) that can be diminished or avoided by subject withdrawal. Discussion with Obagi prior to withdrawal is preferred.
- Subject withdrawal is in the best interest of the health of the subject. A withdrawal for medical reasons should document the specific condition for removing the subject. Discussion with Obagi prior to withdrawal is preferred.
- Lost to follow-up.
- Death.

The final safety evaluation required by the protocol will be performed at the time of the early termination, if possible. All subject withdrawals will be fully documented.

Subjects who discontinue prematurely from the study will not be replaced until approved by the sponsor.

8.5.2 SCREEN FAILURES

A screen failure is a subject that is withdrawn from the study for any reason, after signing an Informed Consent Form without being enrolled. The Informed Consent Form signed by the subject should be kept with the source documents for subjects who do not pass the screening procedures. The documentation should include identification of the eligibility criterion or criteria that were and were not met. The subject should not be re-screened for this study without Obagi's approval.

9 TREATMENTS AND STUDY PRODUCTS

9.1 PRODUCT IDENTITY AND TREATMENTS ADMINISTERED

Obagi 360 contains: Obagi Exfoliating Cleanser, Obagi 0.5% retinol, and Hydrafactor SPF30. When used together under the guidance of a dermatologist/physician, these products are anticipated to work synergistically to provide improvement in the appearance of photodamage, fine lines, and wrinkles.

The Exfoliating Cleanser with maltodextrin (and) Eperua Falcata Bark Extract (Appendix 4) is intended to gently exfoliate the skin in preparation for the moisturizing retinol cream. The 0.5% retinol (in both the Moisturizer and the Night Cream; Appendix 5) is intended to improve skin texture and evens out roughness. For protection, the Hydrafactor SPF30 (Appendix 6), is a physical sunblock used as part of the Moisturizer.

9.2 CLINICAL SUPPLIES

Obagi or its designee will supply the Obagi 360 system to the sites.

9.2.1 PACKAGING AND LABELING

The packaging will be clearly labeled with the following information: study number, unique treatment number, contents, and storage instructions. Coordinators will write date dispensed, bottle #, and subject identification information on each package.

Sufficient drug supplies will be packaged and labeled. Kits will be assigned to qualified subjects at the baseline (Day 0) visit. Additional supplies will be sent to the study centers as necessary until the enrollment goal is met.

9.2.2 DISPENSING

The principal investigator or appropriate designee at each site will be responsible for dispensing the Obagi 360 system to the subjects. At baseline, Day 28 and Day 56 visits, the subject will receive a new Obagi 360 system for the following month's use. At the Day 28, 56 and 84 visits, the subject will return the unused portion of the previous month's supply to the site.

9.2.3 STORAGE

All products should be stored at room temperature 15° to 30°C (59° to 86°F). Protect from freezing. Each investigator will keep study drugs in a pharmacy or a locked and secured storage facility, accessible only to those individuals authorized by the investigator to dispense this study product.

9.3 ACCOUNTABILITY

The product will be released to the investigator/pharmacy after approvals of the study protocol have been received by Obagi from the IRB. Product accountability must be maintained for used product as well as the unused product. The principal investigator is responsible for ensuring that accurate records of the receipt of all investigational products are maintained, including date and amount received. Dispensing records of all investigational products will also be maintained including the date, amount dispensed, and the subject receiving the investigational products. All remaining investigational products must be returned to Obagi or its designee or destroyed immediately after the study is completed. Products deliberately and/or accidentally destroyed at shipment or at a study site should be accounted for and documented. The study products must not be used outside the study. All clinical supplies must be accounted for at the termination of the study and a written explanation provided for discrepancies.

9.4 DOSE ADMINISTRATION

The site will provide instructions for the proper application of Obagi 360 system at baseline (Appendix 1). Study product should be applied by the subject for the subsequent days. The subject will be instructed to use the Exfoliating Cleanser in the morning and in the evening. After the Exfoliating Cleanser is used in the morning, the Moisturizing Cream (0.5% retinol with moisturizers and Hydrafactor SPF 30) will be applied. After the Exfoliating Cleanser is used in the evening, the Night Cream (0.5% retinol with moisturizers) will be applied.

Written instructions for the proper administration of study product will be provided to the subject (Appendix 1).

9.5 STUDY RESTRICTIONS

Subjects will be instructed to refrain from use of certain concomitant treatments and medications during the study (Section 10).

9.6 ASSESSMENT OF TREATMENT COMPLIANCE

The subjects will return to for follow up on Day 14, 28, 56, and 84 to ensure compliance to protocol procedures, including refraining from the use prohibited concomitant treatments or medications.

10 CONCOMITANT MEDICATIONS

Medications in use at study entry should be documented on the CRF. Documentation should include medications that subjects take on an elective or as needed basis. If medications are related to a pre-existing (concomitant) condition or disease this condition or disease will be documented on the Medical History page of the CRF. In general, the addition of a concomitant medication upon or after treatment represents a new adverse event. Worsening of a condition present upon entry or noted as medical history also represents a new AE.

The following medications, preparations, and treatments are prohibited during the study as follows:

1. All topical skin care products on the face. Non-medicated facial cleansers are allowed. The use of Latisse is allowed. Makeup is allowed but must be removed for study visits.
2. All facial treatments including toxins, fillers, microdermabrasion, IPL, peels, facials, laser treatments, tightening treatments, and facial laser hair removal. Waxing and threading is allowed.
3. Oral or topical retinoids.
4. Alpha or beta hydroxy acids.

The use of other OTC and prescription medications, exclusive of the medications, preparations, and treatments listed above, are permitted after initiation of the study drug, but must be captured on the appropriate CRF page. If a patient uses any of the above prohibited treatments after initiation of the study drug, contact the medical monitor.

11 ASSESSMENT OF EFFECTS

11.1 INVESTIGATOR'S SKIN GRADING OF PHOTODAMAGE

At the baseline visit the investigator will assess the facial skin for photodamage based on the grading scale below. The grading scale is a static scale. At each subsequent visit, the investigator will assess the facial skin for effects of treatment with the Obagi 360 system using the same scale. No reference to grading at prior visits will be made. Assessment of the components of photodamage will be made on a 7-point scale as shown below.

Investigator's Skin Grading Scale
Manifestations of Facial Photodamage
Overall Rating Scale: 0= None, 1= Minimal, 2-3 = Mild, 4-5= Moderate, 6= Severe

Fine Wrinkling	Number and depth of superficial wrinkles, fine lines typically appearing in periorbital and perioral regions,
Mottled Hyperpigmentation	Assessment of light patchy mottled hyperpigmentation and solar freckling based on qualitative criteria such as area/density of pigment, color intensity, uniformity of distribution
Sallowness	Visual assessment of color tone from pink or rosy to very sallow or pale- The opposite of radiance
Loss of texture	Visual assessment of surface properties of the skin, i.e., skin grain and smoothness
Pore visibility	Appearance of pores, especially on the nose and cheek areas
Breakouts	Small non-inflammatory acneic lesions

11.1.1 INVESTIGATOR FACIAL PHOTODAMAGE CHARACTERISTICS ASSESSMENT

Efficacy evaluations for each of the following dermatological characteristics will be conducted according to Table 2: fine wrinkling, mottled hyperpigmentation, sallowness, loss of texture, pore visibility, and breakouts.

Table 2 Investigator's Skin Grading Scale

Investigator Assessment of Manifestations of Facial Photodamage						
	FACIAL PHOTODAMAGE SKIN GRADING SCORE					
Severity	FINE WRINKLING (circle one)	MOTTLED HYPER-PIGMENTATION (circle one)	SALLOWNESS (circle one)	LOSS OF TEXTURE (circle one)	PORE VISIBILITY (circle one)	BREAKOUTS (circle one)
None	0	0	0	0	0	0
Minimal	1	1	1	1	1	1
Mild	2	2	2	2	2	2
Mild	3	3	3	3	3	3
Moderate	4	4	4	4	4	4
Moderate	5	5	5	5	5	5
Severe	6	6	6	6	6	6

11.1.2 INVESTIGATOR ASSESSMENT OF OVERALL INTEGRATED FACIAL PHOTODAMAGE

Efficacy evaluation for overall integrated facial photodamage will also be conducted according to Table 3.

Table 3 Investigator Assessment of Overall Integrated Facial Photodamage

Score	Overall Facial Photodamage
0	None
1	Minimal
2	Mild
3	
4	Moderate
5	
6	Severe

11.2 PHOTOGRAPHS

The following instructions will be used to obtain photographs at each visit. Detailed instructions are provided in the Photography Manual.

1. Instruct subject to remove all makeup including eye makeup and lipstick.
2. Wipe subject's face with make-up remover to remove any residual makeup and apply blotting papers to eliminate shine (both items will be provided by sponsor).
3. Clear all hair away from face with headband (provided by sponsor).
4. Place white drape over subject's clothes (provided by sponsor).
5. Using the Visia camera system (Canfield Scientific), be sure the stool height is adjusted, the subject is sitting up straight and the subject has a neutral, relaxed facial expression with eyes open. Each subject will have a frontal, right oblique, and left oblique picture taken with specified filters: Standards, parallel polarized, perpendicular polarized, UV, fluo and UV spots.
    - For frontal view: subject's chin should be centered and gently resting in the chin cup. The subject's head, neck and spine should be aligned and she should face the booth squarely in the appropriate direction for the view.
    - For right oblique view: position the forehead support and the chin cup on the right side of the device. Have subject rest chin in cup and tilt forward until positioned.
    - For left oblique view: position the forehead support and the chin cup on the left side of the device. Have subject rest chin in cup and tilt forward until positioned.

All images will be captured on a flash drive and sent to the sponsor at the end of the first month of the study, the middle of 2 month of the study and at the end of the study.

11.3 SUBJECT'S SELF-ASSESSMENT

At each visit after baseline the subject will complete a self-assessment using the scales provided in Appendix 2 and/or Appendix 3, based on visit requirements.

12 SAFETY EVALUATIONS

12.1 SAFETY ASSESSMENTS – ADVERSE EVENTS (AE)

An AE is any untoward medical occurrence in a subject or clinical investigation subject administered a study product and which does not necessarily have a causal relationship with the study product. An AE can therefore be any unfavorable and unintended sign (including a clinically significant abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational or marketed study product, whether or not considered related to the investigational or marketed study product.

AEs include any illness, sign, symptom, or out-of-range AND clinically significant laboratory finding that has appeared or worsened during the course of the clinical study, regardless of causal relationship to the study product(s). The collection of non-serious AE information should begin at initiation of study product. Serious AEs (SAEs) should be collected from the time that the subject provides informed consent, which is obtained prior to the subject's participation in the clinical study, i.e., prior to undergoing any study-related procedure and/or receiving investigational product, through and including 30 calendar days after the last administration of the investigational product. Any SAE occurring after study completion must be promptly reported if a causal relationship to investigational product is suspected.

An evaluation of adverse experiences will be performed at each visit. The subject will be questioned to determine if any adverse events have been experienced since the last visit. All adverse events, regardless of perceived relationship to investigational product, will be reported and recorded on the appropriate case report forms. Any significant new abnormality will be recorded and followed until the abnormal finding returns to normal for that subject.

When a concomitant medication/therapy is reported during the study that is not related to medical history, a corresponding Adverse Event form will be completed and the reason for the treatment documented.

When a drug-related adverse event persists at the end of the study, the investigator will conduct follow-up contacts with the subject until the investigator/sponsor agree the event is satisfactorily resolved and/or stabilized.

AEs should be followed to resolution or stabilization, and reported as SAEs if they meet the criteria for SAE. The investigator will instruct the subject to report any adverse events that may occur during the study. At each visit, the investigator should ask the subject, in a non-directive fashion, about any change in the subject's overall condition since the previous visit. All AEs will be recorded in the CRF.

Each AE, which appears to be independent of any prior event, will be reported separately. The description will include the nature of the adverse event, the date of onset, the severity (Section

14.1.1) of each event, the investigator's opinion regarding the likelihood of causal relationship (Section 14.1.2) to study drug, the course of action taken, the date of resolution, and the outcome of the event.

12.1.1 SEVERITY OF ADVERSE EVENTS

The severity of an adverse event is to be indicated by the investigator according to the following scale:

1	Mild	Awareness of sign or symptom, but easily tolerated
2	Moderate	Discomfort enough to cause interference with usual activity
3	Severe	Incapacitating with inability to work/perform usual activity or to significantly affect clinical status

12.1.2 RELATEDNESS OF ADVERSE EVENT

The relationship of an adverse event to investigational product is to be assessed by the investigator according to the following definitions:

Related: There is a relationship between the event and treatment with the investigational product or there is a reasonable possibility that there is evidence to suggest a causal relationship, follows a temporal relationship of the event to study drug administration and cannot be reasonably explained by other factors (such as the subject's clinical state, concomitant therapy and/or other interventions). The following types of evidence would suggest a causal relationship between investigational product and AE: a single occurrence of an event that is uncommon and known to be strongly associated with drug exposure (angioedema, hepatic injury, Stevens-Johnson Syndrome), one or more occurrences of an event that is not commonly associated with drug exposure, but is otherwise uncommon in the population exposed to the drug (tendon rupture), an aggregate analysis of specific events observed in a clinical trial that indicated those events occur more frequently in the drug treatment group than in a concurrent or historical group.

Not Related: There is not a possibility that the AE is related to the investigational product. There is Data is available to clearly identify an alternative cause for the event (e.g., antigen in a case of suspected drug-induced hepatitis, hemorrhage due to mechanical injury)

Note: An alternative etiology must be provided by the investigator if the event is deemed Not Related

12.1.3 SERIOUS ADVERSE EVENTS (SAE)

If either the sponsor or the investigator believes that the event met seriousness criteria, the event must be considered serious and evaluated by the sponsor for expedited reporting (21 CFR 312.32(a)).

As with the definition of serious, the determination of whether an AE is life-threatening can be based on the opinion of either the investigator or sponsor (21 CFR 312.32(a)).

A SAE is defined (21 CFR 312.32) as any untoward medical occurrence occurring at any dose that results in any of the following outcomes:

- results in death,
- is life threatening (defined as an event in which the Subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe),
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity,
- results in a congenital anomaly or birth defect, or
- Is an important medical event (defined as a medical event(s) that may not be immediately life-threatening or result in death or hospitalization but, based upon appropriate medical and scientific judgment may jeopardize the patient/Subject or may require medical or surgical intervention to prevent one of the other serious outcomes listed in the definition above). Examples of such events include, but are not limited to, allergic bronchospasm requiring intensive treatment in an emergency room or at home; blood dyscrasia or convulsions that do not result in inpatient hospitalization; the development of drug dependency or drug abuse.
- Hospitalization solely for the purpose of diagnostic tests, even if related to an AE, elective hospitalization for an intervention which was already planned before the inclusion of the subject in the study, and admission to a day-care facility may not themselves constitute sufficient grounds to be considered a SAE. Hospitalization is defined as being admitted to a hospital as an in-patient for greater than 24 hours.

Any SAE that occurs during the study whether related to the treatment or not, expected or not, will be reported immediately (within 24 hours of knowledge of occurrence) by telephone and confirmed facsimile transmission/email to the Medical Monitor and/or Project Manager listed in this protocol. If only limited information is initially available, follow-up reports are required.

Information regarding serious adverse events will be transmitted to the sponsor using the Serious Adverse Event From, which must be signed by a member of the investigational staff. The initial report of a serious adverse event may be made by facsimile (fax) or telephone. It is

preferable that serious adverse events be reported via fax. Subsequent to a telephone report of a serious adverse event, A Serious Adverse Event Form must be completed by the investigational staff and transmitted to the sponsor within 1 business day. Serious adverse events require notification within 1 business day to the Sponsor or its designated representative beginning from the time that the subject provides informed consent, which is obtained prior to the subject's participation in the clinical study, i.e., prior to undergoing any study-related procedure and/or receiving investigational product, through and including 30 calendar days after the last administration of the investigational product. Any SAE occurring after study completion must be promptly reports if a causal relationship to investigational product is suspected.

The immediate SAE report should be followed-up within one business day by electronic mailing (e-mail) the completed SAE form to: drugsafety.valeant@symogenlimited.com. Please also copy the following email addresses on the distribution of the SAE form: sumeet.auplish@valeant.com; mohammed.merchant@valeant.com; mkaur@medicis.com.

12.1.4 PREGNANCY

All female subjects of childbearing potential must use an effective method of birth control during the course of the study, in a manner such that risk of contraceptive failure is minimized. Abstinence is allowed as a birth control method.

Before enrolling a female subject of childbearing potential in this clinical trial, the Investigator must review the following information about study participation:

- Informed consent/assent requirements
- Contraceptives in current use

Following review of this information and appropriate subject counseling, the Investigator or designee and the subject must sign the Informed Consent before study enrollment.

During the study, all female subjects of childbearing potential should be instructed to contact the Investigator immediately if they suspect they might be pregnant (e.g., missed or late menstrual period).

If a subject or Investigator suspects that the subject may be pregnant prior to study enrollment, the investigational product must be withheld until the results of laboratory pregnancy testing are available. If pregnancy is confirmed, the subject must not receive investigational product and must not be enrolled in the study. If pregnancy is suspected while the subject is receiving investigational product, the investigational product must immediately be withheld until the result of a urine pregnancy test is known. If pregnancy is confirmed, the study drug will be permanently discontinued and the subject will be followed until the pregnancy comes to term. A Pregnancy Report form will be submitted, initially and quarterly through the end of the pregnancy, which includes the outcome of the pregnancy and any complications occurring

during the pregnancy or the delivery. The timelines and sponsor contact(s) for submission of pregnancy related information will follow those of SAEs above.

An event that is serious must be recorded on the Adverse Events CRF and requires expeditious handling to comply with regulatory requirements. All initial SAEs and follow up reports that contain change in causality must be forwarded to Obagi within 1 business day upon receipt of SAE. In addition, the serious adverse event form and other SAE-related forms must be completed accordingly.

Any serious or immediately life-threatening adverse event, including death, occurring while the subject is participating in a clinical study, irrespective of the investigator's opinion of causality (considered related or unrelated), will be reported immediately (within 24 hours of knowledge of occurrence) by telephone and confirmed facsimile transmission/email to the medical monitor listed in this protocol. If only limited information is initially available, follow-up reports are required. In the event of death, if an autopsy is performed, a copy of the report should be sent to medical monitor / sponsor.

The investigator is also responsible for notifying the IRB within the time frame established by the IRB.

12.2 TOLERABILITY EVALUATIONS

The investigator will assess the tolerability of the Obagi 360 system at each visit. Tolerability will be graded on a 4-point scale (0 – none to 3 – severe) for each of the following:

- Dryness/Scaling
- Erythema
- Burning/Stinging
- Itching

13 STUDY PROCEDURES BY VISIT DAY

The following sections describe in detail all study procedures. A flow chart of all study procedures is presented in Table 1. Source documents will be completed at each subject's visit, and the data captured in the source documents will be subsequently entered onto case report forms (CRFs) by the investigator or designee.

13.1 VISIT 1/BASELINE VISIT (STUDY DAY 0)

The following pre-study screening procedures should be completed prior to initiating study treatment:

1. Obtain a signed and dated subject informed consent form and authorization to use and disclose medical information prior to performing any study-specific procedures;
2. Obtain a signed and dated Photographic Release Form prior to obtaining any photographs
3. Collect demographic information including date of birth, sex, race, ethnicity and Fitzpatrick skin type;
4. Collect a medical history (only relevant, current/ongoing diseases/conditions and past surgeries/procedures as determined by the investigator);
5. Review inclusion and exclusion criteria;
6. Upon qualifying for the study, subjects will be assigned a study number (See Section 8.4);
7. Conduct Investigator's Skin Grading Assessment, see Section 11.1;
8. Obtain photographs. For details instruction on obtaining photographs, see Section 11.2;
9. A urine pregnancy test will be performed on females of child-bearing potential.
10. Review and record concomitant medications;
11. Dispense study product. Complete the product accountability CRF form;
12. Instruct subject in the application of the Obagi 360 system and provide written instructions;
13. Schedule the next visit with the subject on study Day 14 (± 2 days).

13.2 VISITS 2 THROUGH 5 (STUDY DAY 14 [± 2 DAYS], AND STUDY DAYS 28, 56, AND 84 [± 5 DAYS])

The following procedures will be performed at these visits:

1. Conduct Investigator's Skin Grading Assessment, see Section 11.1;
2. Obtain photographs. For details instruction on obtaining photographs, see Section 11.2;
3. A urine pregnancy test will be performed on females of child-bearing potential at the End of Study Visit.
4. Conduct subjects' self-assessment see Section 11.3, Appendix 2 and Appendix 3;
5. Assess tolerability of the Obagi 360 system;
6. Review and record concomitant medications;
7. Review and record adverse events;
8. Dispense/collect study product. Complete the product accountability CRF form;
9. Review with subject the application of the Obagi 360 system;
10. Schedule the next visit with the subject or end subject participation at Visit 5.

14 STATISTICAL METHODS

14.1 ANALYSIS POPULATIONS

All enrolled subjects will be used to summarize subject disposition, demographic and baseline characteristics, medical history, and prior/concomitant medications.

The analysis population will use all available subject data to evaluate the effect of the Obagi 360 system for photodamage.. No imputation of missing data will be performed.

The safety population includes all enrolled subjects who applied any amount of study product. This population will be used for product exposure and all safety analyses.

14.2 STATISTICAL ANALYSIS

14.2.1 SUBJECT ACCOUNTABILITY

Subject disposition and reasons for discontinuations will be summarized.

14.2.2 DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Demographics and baseline characteristics will be summarized.

14.2.3 ANALYSIS OF IMPROVEMENT IN PHOTODAMAGE BY INVESTIGATOR

For each of the components of the Investigator's Skin Grading Assessment for improvement in photodamage, the data will be summarized in the format shown in Table 4.

In the case of the Investigator's Assessments asked at each timepoint, a Paired T-Test will be used to compare the individual scores at each time point relative to their respective baselines for each treatment cell. The net change scores for each attribute will be shown as a distribution and converted to the number of subjects who showed "improvement", "stayed the same" or "worsened".

For all analyses unless otherwise specified, a two tailed $p < 0.05$ will be taken as the level of significance.

Table 4 Format for Summary of Investigator's Skin Grading Scale

Investigator's Skin Grading Skin Grading Component (e.g., Sallowness)		
	Mean ± S.D.	**P-value**
Baseline		--
Day 14		
Day 28		
Day 56		
Day 84		
Net Change from Baseline		
Day 14		--
Day 28		--
Day 56		--
Day 84		--

Distribution of (Net Change) Scores									
	-4	-3	-2	-1	0	+1	+2	+3	+4
Day 14									
Day 28									
Day 56									
Day 84									

	Improved	**=**	**Worse**
Day 14			
Day 28			
Day 56			
Day 84			

14.2.4 ANALYSIS OF SUBJECT'S SELF-ASSESSMENT

For the Subject's Self-Assessment, each question will be summarized separately using the proportion of subjects replying for each category (e.g., Strongly agree, Agree, Indifferent, Disagree, Strongly disagree) by visit. No statistical testing will be performed on the Subject's Self-Assessment.

14.2.5 ANALYSIS OF SAFETY

14.2.5.1 Analysis of Adverse Events

Safety analysis will include assessment (number and %) of all treatment-emergent AEs, any serious AEs, treatment-related AEs, and AEs leading to study discontinuation for each treatment group.

All AEs will be coded by the Medical Dictionary for Regulatory Activities (MedDRA).

Treatment-emergent adverse events (TEAEs) are defined as those AEs that either have an onset time on or after the start of study drug until the end of study.

Treatment-emergent AEs will be summarized for each treatment group by the overall incidence of at least one event, incidence by system organ class, and incidence by system organ class and

preferred term. Each subject will be counted only once for each of the rates, regardless of the number of occurrences (events) the subject experiences. Treatment-emergent AEs will be summarized by severity and by relationship to study product.

14.2.5.2 Analysis of Tolerability

Tolerability will be assessed using the scale in Section 12.2. For each of the assessments, the proportion of subjects experiencing none, mild, moderate, and severe will be summarized by visit.

14.3 SAMPLE SIZE

Forty subjects will be enrolled. Forty subjects are adequate to obtain information on the anti-aging effects of the Obagi 360 system.

14.4 INTERIM REPORT

Interim analyses are not planned for this study.

14.5 DATA HANDLING

Standards for data handling will be established in the data management plan. Study data will be reviewed, according to these data management guidelines. Case report forms will be monitored and audited by Obagi. Data management will provide queries for discrepancies requiring study center resolution. Upon receipt of resolved queries, appropriate updates, based on the response, will be made to the database. New or changed information in each query must be verifiable in the source documentation.

15 MANAGEMENT/COMPLIANCE/QUALITY ASSURANCE

15.1 STUDY TERMINATION

The protocol may be terminated by Obagi immediately upon notice to the investigator, if any of the following conditions occur:

- If the emergence of any adverse reaction or side effect with the study product in the study or elsewhere is of such magnitude or incidence in the opinion of Obagi to support termination.
- Obagi may also terminate the study for any internal business reasons at Obagi's sole discretion.
- If Obagi fails to secure compliance with requirements of the protocol and GCP at a specific site the study must be terminated at that site.

In the event of a termination, Obagi will provide information on the handling of currently enrolled subjects who have not completed the protocol.

15.2 MONITORING

Monitoring visits provide Obagi with the opportunity to evaluate the progress of the study, verify the accuracy and completeness of CRFs, assure that all protocol requirements, investigator's obligations are being fulfilled, and resolve any inconsistencies in the study records. Monitoring is required by federal regulations. The investigator will allow Obagi representatives to periodically review, at mutually convenient times during the study and after the study has been completed, all CRFs and corresponding portions of office, hospital, and laboratory records (source documents) of each study participant. CRFs must be up-to-date and available for each monitoring visit. The investigator or appropriate personnel must be available during the monitoring visits.

15.3 OBAGI AUDITS/QUALITY ASSURANCE

Obagi may require a site audit for cause The investigator or appropriate personnel must be available during audits.

Quality assurance includes verification of data entered into the study database via the query process. In the event of inconsistent or missing data, the discrepancies will be clarified by the issuing of query forms to the site for resolution. The study database cannot be closed until all queries are addressed. Prompt response to queries is required.

15.4 CASE REPORT FORMS (CRF)/SOURCE DOCUMENTS

Case report forms (CRFs) will be used for recording all data from source documents for each subject. Source documents are the point of first entry for all data collected, and may include written charts, laboratory results, diaries and questionnaires. Relevant data will be entered into the case report form system. Data should be entered within one week of each subject's visit, if possible. Whenever possible, an original recording of an observation should be retained as source document. Specific training will be provided to center personnel prior to study start.

The investigator will ensure that the CRFs are properly completed for all subjects who have signed an informed consent form. CRFs will be monitored against source documents. If data in the CRF are not duplicated in a source document, a source document should be created and maintained by the site to capture that information. Source documentation for subjects include but are not limited to the physician's patient records or hospital computer database, diaries, photographs, x-rays and electrocardiograms. All source documents will be maintained at the study site.

The principal investigator or delegate may enter corrections in the CRFs. Each change will be initialed and dated in black ink by the person performing the change. The final CRF will be approved by the principal investigator by signature.

15.5 STUDY RECORDS/SOURCE DOCUMENTS MAINTENANCE

All records pertaining to the conduct of the clinical study, including signed CRFs, informed consent forms, drug accountability records, source documents, and other study documentation must be retained until notified by Obagi

In any case, the investigator must not destroy any records associated with the study without contacting Obagi and receiving approval. The investigator must notify Obagi in the event of accidental loss or destruction of any study records. If the investigator leaves the institution where the study was conducted, Obagi must be contacted to arrange alternative record storage options. Study documentation includes, but is not limited to, all CRFs, data correction forms, source documents, monitoring logs, Obagi-investigator correspondence, protocols and amendments, clinical supplies receipt, dispensing and final disposition records, IRB correspondence and approvals, signed consent forms, and Statement of Investigator forms.

15.6 PROTOCOL COMPLIANCE

The investigator must comply with all terms of the protocol. All protocol deviations must be documented. The subject is also expected to comply with the protocol as set forth in the informed consent and implicit in subject participation. During the recruitment phase, it is imperative that the subjects understand that they are expected to return for the designated follow-up treatment and evaluations, and the importance of doing so. If the subject is not willing to participate in the follow-up, he/she must be excluded from participation.

15.7 PROTOCOL AMENDMENTS

Any amendment to the protocol, with the exception of those which remove an emergency or immediate health risk to the subject, must be approved in writing by the IRB and Obagi before implementation. The provisions for emergency amendment require, if feasible, prior contact with Obagi, and the IRB. If contact is not feasible before the change, Obagi and the IRB must be contacted as time permits. All changes to the final study protocol must be documented in a written protocol amendment either before implementation or, in the event of an immediate health hazard, within 5 working days.

15.8 DEVIATION FROM THE PROTOCOL

The investigator should not deviate from the protocol. In medical emergencies, the investigator will use medical judgment and remove the participant from immediate hazard as discussed above.

Deviations from the protocol may nevertheless occur (e.g., subject failure to attend scheduled visit during a visit window, accidental omission of notations from the CRF, misunderstanding with regard to visit procedures). Any deviation from the protocol must be fully recorded in the

source documents to permit analysis of the effect of the deviation on the data collected, subject safety, or data analysis.

Deviations from the protocol must be reported to the IRB according to their policies.

15.9 CONFIDENTIALITY/STUDY SUBJECT IDENTIFICATION

All information not previously published concerning the test product and Obagi's research, including patent applications, manufacturing processes, basic scientific data, this protocol, or other information provided by Obagi, is considered confidential and should remain the sole property of Obagi, pursuant to the written contractual agreement between these parties which governs the handling of Proprietary and Confidential Commercial Information. The investigator agrees to use the information only in connection with this study and will not use it for other purposes without written permission from Obagi. The terms of the Investigator Agreement govern the definition and handling of confidential information.

It is understood by the investigator that data from the study may be used by Obagi in connection with the development of the study product. Data and information may therefore be disclosed as required to other investigators or be placed in the product label or other information disseminated by Obagi. By signing this protocol, the investigator affirms that study subject data, and especially study subject identifier information, will be maintained in confidence as set forth in the protocol and any written contractual agreement. Confidential information will be divulged to the IRB, IEC, or similar expert committee; affiliated institutions; and employees only under an appropriate understanding of confidentiality with such board or committee, affiliated institution and employees. By signing the protocol, the investigator agrees that, within local regulatory restrictions and ethical considerations, Obagi or representatives of Obagi, or applicable regulatory agency may review study documents, including study subject identifying and other confidential information, in order to verify CRF data and in accordance with federal regulations. Obagi shall, to the extent feasible, protect study subject identifier information.

15.10 COMPLIANCE WITH THE LAW

By signing this protocol, the investigator agrees to conduct the study in an efficient and diligent manner and in conformance with the protocol, generally accepted standards of good clinical practice, conditions of protocol approval imposed by the IRB, and all applicable federal, state and local laws, rules and regulations. The investigator shall prepare and maintain complete and accurate documents relating to the investigation in compliance with the protocol, GCP standards and applicable federal, state and local laws, rules and regulations including all correspondence with another investigator, an IRB, Obagi or monitor and each subject's case history and exposure to the investigational product as required on the CRFs and maintain all supporting data in subject records. For each study subject participating in the study, the investigator will promptly submit all original CRFs to Obagi. Furthermore, the investigator also agrees to submit other necessary documents as required by this protocol following completion or termination of the clinical

evaluation or as otherwise required pursuant to any agreement with Obagi or Representative of Obagi. Study documents will be promptly and fully disclosed to Obagi by the investigator upon request for inspection, copying, review and audit at reasonable times by representatives of Obagi. The investigator agrees to promptly take any reasonable steps, requested by Obagi or representative of Obagi, as a result of an audit, to cure deficiencies in the document or CRFs. The investigational product will be used only on subjects properly enrolled in the study. Upon completion or termination of the study or the investigator's participation in the study, the investigator will account for and/or return to Obagi any remaining supply of the investigational product as Obagi directs. The investigator will maintain records of receipts, type and quantity, dates of receipt, batch numbers, and the names of all persons who may have received used or disposed of each investigational product and whether and how any such products were returned, repaired, or destroyed. The study product will be stored in a secure location. The investigator shall record any deviations from protocol management of a subject. The investigator will maintain a signed copy of the protocol.

15.11 FINANCIAL DISCLOSURE

Regulation requires sponsors to obtain financial information from investigators participating in covered clinical studies. Each Principal Investigator and Sub-Investigator is required to provide financial disclosure information and to promptly update Obagi with any relevant changes to their financial information throughout the course of the clinical study and for up to one year after its completion.

15.12 INVESTIGATOR AND SITE QUALIFICATIONS; DEBARMENT

Persons debarred from conducting or working in clinical studies by any court or regulatory agency will not be allowed to conduct or work on the study. The investigator will immediately disclose in writing if any person who is involved in conducting the study is debarred or if any proceeding for debarment is pending or, to the best of the investigator's knowledge, threatened. To that end, the investigator has not been personally and will not use as an assistant any person who is debarred from participation in clinical trials under the Generic Drug Enforcement Act of 1992 (21 USC § 301 et seq.) or any other provision of law (e.g., 21 CFR § 312.70). If such a proceeding should commence, involving the investigator or any assistant, the investigator will promptly inform Obagi. Further, the investigator has not and no person or entity affiliated with the investigator or under the investigator's supervision is excluded from participation in a Federal Health Care Program as defined in 42 U.S.C. § 1320a. The investigator has never been convicted of a felony.

The investigator will provide a signed, accurate, non-misleading, and current copy of his or her curriculum vitae to Obagi that demonstrates his or her qualifications to conduct this study and, if requested, will provide a list of sub-investigators or health professionals who are assisting in the conduct of this study and documentation of their qualifications.

The facilities where this study will be conducted have the necessary subject population and personnel to properly conduct the study.

16 REFERENCE LIST

1. Griffiths CE, Wang TS, Hamilton TA et al. A Photonumeric Scale for the Assessment of Cutaneous Photodamage. Arch Dermatol. 1992; 128: 347-351.

2. Kappes UP, Elsner P. Clinical and Photographic Scoring of Skin Aging. Skin Pharmacol Applied Skin Physiol 2003; 16: 100-107.

3. Larnier C, Ortonne JP, Verot A, et al. Evaluation of Cutaneous Photodamage Using a Photographic Scale. Br J Dermatol 1994; 130: 167-173.

APPENDIX 1: INSTRUCTION FOR APPLICATION OF STUDY PRODUCT

Please follow these instructions carefully. Contact the study staff at the telephone number noted below if you have any questions about the study:

Contact: _____ **Telephone:** _____

Morning Cleansing and Application Day Cream with SPF: once a day in the am (morning)

STEP 1: Wet face and hands with lukewarm water. Dispense a full 1-pump dose of the Exfoliating Cleanser into the palm of your hand and gently rub over your entire face, taking care to avoid the eyes. Rinse completely with lukewarm water and gently pat your face dry with a towel.

STEP 2: Using your fingertips, apply a full 1-pump dose of the Moisturizer to the entire face and forehead, avoiding the eye area.

Evening Cleansing and Application Night Cream: once a day in the pm (evening)

STEP 1: Thoroughly remove all eye makeup. Wet face and hands with lukewarm water. Dispense a full 1-pump dose of the Exfoliating Cleanser into the palm of your hand and gently rub over your entire face, taking care to avoid the eyes. Rinse completely with lukewarm water and gently pat your face dry with a towel.

STEP 2: Using your fingertip, gently a full 1-pump dose of the Night Cream to the entire face and forehead, avoiding the eye area.

For all products, avoid contact with eyes. Rinse eyes thoroughly if contact occurs.

APPENDIX 2: SUBJECT'S SELF-ASSESSMENT OF IMPROVEMENT

Questionnaire – Day 14 and Day 28

SUBJECT QUESTIONNAIRE - SELF-ASSESSMENT OF IMPROVEMENT

(THE SUBJECT SHOULD COMPLETE THIS QUESTIONNAIRE AND INITIAL THE BOTTOM OF THIS PAGE IN THEIR OWN HANDWRITING)

Have you noticed an improvement to your skin appearance? ☐ Yes ☐ No

If Yes, please rate the speed with which you saw an improvement in your facial skin:

When:

- ☐ Immediately
- ☐ Within 1 day
- ☐ Within 1 week
- ☐ Within 2 weeks
- ☐ Within 4 weeks

Subject to Initial: _____

APPENDIX 3: SUBJECT'S SELF-ASSESSMENT

(PART 1)

Questionnaire – Day 14, 28, 56 and 84/EOS

SUBJECT'S SELF-ASSESSMENT QUESTIONNAIRE (PART 1)

(THE SUBJECT SHOULD COMPLETE THIS QUESTIONNAIRE AND INITIAL THE BOTTOM OF THIS PAGE IN THEIR OWN HANDWRITING)

For each question, please put a check mark (√) in the column you agree with the most, use one check mark for each statement.

Please rate your agreement with the following statements:

	Strongly Agree	Agree	Indifferent	Disgree	Strongly Disagree
I am satisfied with the overall results this product provides					
My lines and wrinkles are less visible					
My face appears more firm					
My skin tone has become more even					
My skin brightness has increased					
My skin texture has improved					
My skin looks refreshed					
My skin feels more resilient					

Subject to Initial: _____

Appendix 3: Subject's Self-Assessment

(PART 2)

Questionnaire – Day 14, 28, 56 and 84/EOS

SUBJECT'S SELF-ASSESSMENT QUESTIONNAIRE (PART 2)

(THE SUBJECT SHOULD COMPLETE THIS QUESTIONNAIRE AND INITIAL THE BOTTOM OF THIS PAGE IN THEIR OWN HANDWRITING)

For each question, please put a check mark (√) in the column you agree with the most, use one check mark for each statement.

Please rate your agreement with the following statements:

	Strongly Agree	Agree	Indifferent	Disagree	Strongly Disagree
My skin clarity has improved					
My face feels rejuvenated					
My skin has a youthful glow/radiance					
My skin vitality has increased					
My skin looks and feels more hydrated					
My pores are less visible					
My breakouts are less visible					
My breakouts are less frequent					
My skin looks and feel smoother					

Would you recommend this product to a friend?	☐ Yes	☐ No
Would you want to purchase this product?	☐ Yes	☐ No
Would you continue using this product if made available?	☐ Yes	☐ No

Subject to Initial: _____

APPENDIX 4: INGREDIENT LIST – EXFOLIATING CLEANSER

Ingredients:

Water (Aqua), Polyethylene, Glycerin, Oxidized Polyethylene, Decyl Glucoside, Lauryl Glucoside, Sodium Cocyl Isethionate, Cocamidopropyl Betaine, Sodium Lauroamphoacetate, Soduim Methyl Cocoyl Taurate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Papain, Algin, Panthenol, Sodium PCA, Sodium Hyaluronate, Sodium Hydroxide, Disodium EDTA, 1,2-Hexanediol, Carbomer, Chlorphenesin, Ethylhexylglycerin, Hexylene Glycol, Caprylyl Glycol, Phenoxyethanol, Limonene, Fragrance (Parfum).

APPENDIX 5: INGREDIENT LIST - 0.5% RETINOL

INGREDIENTS:

Water (Aqua)
Allyl Methacrylates Crosspolymer
Caprylic/Capric Triglyceride
Ascorbic Acid
Butylene Glycol
Cyclohexasiloxane
BHT
Bisabolol
Butyrospermum Parkii (Shea) Butter
Stearic Acid
Caprylyl Glycol
Glyceryl Acrylate/Acrylic Acid Copolymer
Dimethicone/Vinyl Dimethicone Crosspolymer
Stearyl Alcohol
Polysorbate 60
Phenoxyethanol
Cyclopentasiloxane
Hexylene Glycol
Sorbitol
Dipotassium Glycyrrhizate
Disodium EDTA
Ethylhexylglycerin
Glycerin
Glyceryl Stearate
Triethanolamine
Carbomer
Tocopheryl Acetate
Carthamus Tinctorius (Safflower) Seed Oil
Calendula Officinalus Flower Extract
Camellia Sinensis Leaf Extract
Polysorbate 20
Camellia Oleifera Leaf Extract
Retinol
Sodium Hyaluronate
Dimethicone
Chamomilla Recutita (Matricaria) Flower Extract

APPENDIX 6: INGREDIENT LIST – HYDRAFACTOR SPF30

Active ingredients:

Avobenzone 1.0%
Octinoxate 7.5%
Octisalate 5.0%
Oxybenzone 5.0%

Inactive ingredients:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Caesalpinia Spinosa Gum, Caprylyl Glycol, Carbomer, Dextrin, Disodium EDTA, Eperua Falcata Bark Extract, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hydrolyzed Caesalpinia Spinosa Gum, Phenoxyethanol, Pichia/Resveratrol Ferment Extract, Polysorbate 20, Sodium Hyaluronate, Sodium Hydroxide, Sorbitan Oleate, Tocopheryl Acetate, Ubiquinone, Water.