Step by Step on How to be US Claims-Compliant Using Claims to Bolster Sell-through and Mitigate Legal Risk

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15.3

(in 1997) Alternation



the Benchmarking Company Beauty & Personal Care Consumer Research

The Benchmarking Company is a bi-coastal beauty and personal care consumer research firm with a proven track record in cosmetics, skincare, beauty devices, body care, hair care, nail care, fragrance and wellness/personal care.

Laser focused on providing:

- Quantitative research
- Qualitative research
- In-home beauty and personal care product testing

Benefits:

- Proof of efficacy
- Sell-in
- Sell-through
- Consumer insights
- Validation
- Risk mitigation

Understanding the beauty consumer is what we do.



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What We Will Cover Today

- Who is the US Beauty Buyer
 - Why Are Claims Critical
- Claims that Connect w/Consumers
 - A Regulatory Primer
 - Best Practices for Crafting Claims
 - Leveraging Claims to Drive Consumer Demand

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WHO IS THE US BEAUTY BUYER?



Who is the US Beauty Enthusiast

Ginger Gen Z (18-24)*

- Born with smart devices and prefers shopping with this method
- The "selfie" generation thrive to look their best for photos
- 91% of Gen-Z are highly influenced to purchase a beauty product as a result of reading positive reviews
- Top 5 ways she describes herself: Passionate, health-minded, family oriented, trendy and busy
- Is price sensitive
- Looks for animal cruelty logo on BPC products

Maddie Millennial (25-39)

- First generation to adopt widespread cell phone usage
- She is swayed by what is trending in social media
- 88% of Millennials are highly influenced to purchase a beauty product as a result of reading positive reviews
- 59% are early adopters of new skincare trends
- Is influenced to purchase if it is a new product on the market
- Top 5 ways she describes herself: family-oriented, healthminded, busy, passionate and frugal





Who is the US Beauty Enthusiast, cont.

Jessie Gen-Xer (40-54)

- Generation that shops the most frequently
- Are more likely to be influenced to purchase by a salesperson knowledge of a brand and product benefits
- Top 5 ways she describes herself: family oriented, passionate, health minded, busy and focused.
- Are more likely to purchase natural/organic BPC every time they shop than other generations
- 44% use homeopathic remedies regularly
- 65% use natural skincare products on a regular basis

Barbie Boomer (54+)

- Disposable income and still buying big
- Looks for expected benefits and a list of ingredients on beauty packages
- Takes supplements
- Purchase a product from a brand because they are familiar with the brand
- Top 5 words she uses to describe herself: familyoriented, health-minded, spiritual, passionate and environmentally conscious





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Her Expectations

I expect products to...

- **95%** do exactly what the package says it will do
- 84% to have product reviews and consumer claims
- **82%** to be accessible, available where I shop
- 73% be cruelty free/not tested on animals

I expect brands to ...

- Show me the reviews and ratings
- Deliver highly efficacious products
- Give me PROOF of efficacy

The Importance of Knowing Your Target Consumer

- **1.** What compels her to buy?
- 2. What turns her on and what turns her off?
- **3.** What is important to her?
- **4.** What are hot button issues for her relative to beauty?
- 5. Where does she shop?
- 6. How does she research her products?
- 7. What influencers her most in her purchase decisions?



Answers to these questions help brands craft powerful claims that speak to her on an emotional level where and when she shops.

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WHY ARE CLAIMS CRITICAL?



93% LOOK FOR EFFICACY CLAIMS BEFORE PURCHASING A OF WOMEN BEAUTY PRODUCT

86% MAKE BEAUTY BUYING DECISIONS WHILE STANDING OF WOMEN AT THE BEAUTY COUNTER



To win in today's beauty market, you need 5-STAR CONSUMER CLAIMS.



Claims Influence Men Too

89% find consumer claims important when buying a high cost personal care item
83% trust 'men like them' saying that a product works more than a brand saying the same thing

91% would be willing to pay more for a product if they knew it worked and delivered on its promises

Data based on a May 2017 poll of 370 US males ages 18+ who regularly purchase personal grooming products

Claims Deliver Powerful Testimonials



Thanks for the FlashPatch Lip Gel love, Lauren! "these lip masks from @patchology are definitely a new favorite of mine! *** i have been using every night before bed and my lips are getting so much softer

- Real user experiences
- Real user feedback
- Feedback supports, debunks, validates or unearths new benefits or results
- Provides powerful testimonials
- Testimonials used for retail channel requirements (i.e. HSN, QVC, ShopHQ, onair DTC)

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The Benefits of Claims



Insights

Risk Mitigation

Third-party validation

Marketing Claims

Proof Comes in Many Forms

Consumer Claims

Genius Ultimate Anti-Aging Cream Consumer Study Results

Results obtained following a consumer use study of 100 women using the product twice daily.

95%

Dull skin is brighter in 10 days

91% Fragile skin texture appears reinforced within 10 days

95% Skin appears firmer and more resilient, and bounce and suppleness appears restored within 28 days

87%

Forehead wrinkles, creases and lines are visibly minimized within 28 days

Customer Testimonials

**** COULDN'T BELIEVE MY EYES!

I received my first patch as a sample and when I looked in the mirror I couldn't believe my eyes! I looked in the PPEDACE mirror and just kept staring in awe! I felt my face and went in for a closer look. My skin was plumper, bags on Nov 29, 2015 under my eyes filled, fine lines gone! For the first time ever, I immediately got on line and ordered the product and now use my Patchology masks religiously. My skin is visibly more hydrated and looks more alive.

Before & After Photos

Ratings & Reviews



T3 Healthy Hair Set \$250.00 (\$330.00 value) limited edition - online only



Clinical Claims 38.29%

longer lashes





G2G Social Share

Re: Perlier Honey facial skin care Frequent Contributor 07-20-2016 07:32 PM



turquoisebb

Registered: 03-16-2010

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19 🗹 🖸

staying cheerful, You sound like me! My skin is soo dry and even flaky. So I got the 3 piece set and the night oil. WOW! It really helps. I did not get the cream. Skip said it is even better with that. Also said the oil will be featured next month. I'll stock up...that's the very best oil I have ever used. When Amanda said you only need 3 drops, she was right. Glad I got mine at the special pricing.

Consumers Have a *"Prove It"* **Mentality**

89% of women /79% of men say that consumer claims are influential in their decision to purchase beauty/personal care product







$$a = b$$

$$a^{2} = ab$$

$$a^{2} - b^{2} = ab - b^{2}$$

$$a + b)(a - b) = b(a - b)$$

$$a + b = b$$

$$2b = b$$

$$2 = 1$$

(

WHICH CLAIMS CONNECT WITH CONSUMERS AND WHY?



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The Elements of a Believable Claim

Men & women believe consumer claims because they are derived from consumers like them.

What Women and Men Look for in a Claim:

- 97% of women / 91% of men - have similar skin care concerns
- 96% of women / 89% of men - are their same age
- 93% of women / 88% of men - have similar cosmetics needs/ grooming needs
- 82% of women / 75% of men - are of the same ethnicity



of men "I trust a bunch of guys who say the product works more than I trust the brand telling me the product will work."



of women find consumer claims very believable because they are derived from a panel of real women like them.



- The magic number of participants to make a study believable? **Over 100.**
- For a claim to be believable, consumers believe claims percentages must be in the 80s or higher!

Transparency is *Expected*

Consumers expect transparency in all facets of a brand's interactions with the consumer. From disclosing all the ingredients in a product, to how a product claim is derived, today's consumer is an active seeker of information!

- 70% of consumers expect brands to disclose their ingredients not only on product labels but also on the company's website
- 74% of women/62% of men expect the brand to disclose the number of people in a claims study
- 72% of women/54% of men expect disclosure of the attributions of the study participants (i.e. oily skin, acne)
- 66% of women/58% of men expect the brand to disclose the length of the study
- 62% of women/53% of men expect the brand to disclose if the claims study was conducted by a third-party independent research firm





Compelling Claims

Today's consumer is focused on good results fast. Five years ago, anti-aging claims ruled the roost but the claims that resonate today are focused on healthier, purer, cleaner and more youthful skin.

Top coveted claims:

- Radiant looking skin/brighter looking skin (Driver: K-beauty)
- Healthier feeling skin (Driver: organic/natural beauty)
- Younger looking skin/more youthful appearance (Driver: aging of the Baby Boomer)
- Skin feels protected against future aging
- In as little as 14 days, fine lines and wrinkles appear diminished (Driver: Amazon culture – fast delivery!)
- Gentle enough for all skin types (Driver: Microbiome, Probiotics)

HOW DOES A BRAND MITIGATE REGULATORY RISK?



The Regulator: FDA

FDA regulates cosmetics under the authority of two important laws pertaining to cosmetics marketed in the US: The Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act.

The Enforcer: FTC

The **FTC** works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them.

Class Action Lawsuits:

A "class action" lawsuit is one in which a group of people with the same or similar injuries caused by the same product or **action** sue the defendant as a group.







FEDERAL TRADE COMMISSION PROTECTING AMERICA'S CONSUMERS

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Understand Common Pitfalls



Website Claims



Influencers



Healing Effects of Lavender

ing Blood Circula Bair Health Relieving Respiratory Disord Joint and Muscle Pain Relief Treating Fundal a





Competitive Claims

Function Claims

Ingredient Claims

What Claims Can Cosmetics Companies Make?



Though it would be nice to say words like:

- Heal
- Repair
- Regrow
- Regenerate

<u>We just can't!</u> Why?

Because...

According to the FDA a <u>cosmetic</u> is anything intended to be applied to the human body to cleanse, beautify or alter its appearance. But not anything intended to treat or mitigate a disease or to affect the structure of function of the body.

Cold sore treatment heals her lips



Makeup changes her appearance



Properly-worded Claims are Important For Regulatory Compliance & Legal Risk Mitigation

Although marketing claims are important, how brands <u>communicate</u> claims is as important as the claim itself.

"Popular marketing words like recover, heal, and restore can draw regulatory attention and that was evident in 2016, when consumer class suits and FTC and FDA regulatory actions against beauty companies rose steadily." –Ronie Schmelz, Esq., counsel at Tucker Ellis, LLP.



increase in the number of Federal Trade Commission (FTC) warning letters issued to cosmetics companies in 2016 over 2015 for improperly worded claims





Don't Put Your Brand at Risk

2017

- Collagen production/
- stimulation
- Cell regeneration
- Cell turnover
- UV protection/
- prevention of sun damage
- Healing sun damage
- Skin lightening
- Wrinkle reduction

2018

- Ingredient claims
- Natural/Organic claims
- Treatment claims (i.e. acne, inflammation, gingivitis)
- Product names
- Cellulite/Thinning claims

2019

- CBD claims
- Drug claims
- Supplements that imply or explicitly state they solve a medical issue
- Disease prevention



This is to advise you that in April 2019 the Food and Drug Administration (FDA) reviewed your Facebook page, your YouTube channel, and examples of some of the website claims that provide evidence that your product is intended for use as a drug include:

- "Great for connective tissue disorders, pain, and sleep issues"
- "Removes Toxins From The Gut"
- "Removes a variety of Toxin [sic] From the Digestive Tract"

Pitfalls of Ingredient Claims

- Mixing stand-alone ingredients can change formula properties
- Lab concentration levels vs. product concentration
- Drug claims for specific ingredients doesn't mean you can use the same claims for a cosmetic

Language from a formal FDA warning letter:

Lavender [an ingredient in the product]: "[T]his herb has also been used as a remedy for a range of ailments from insomnia and anxiety to depression and fatigue...Lavender has many other health benefits: antibacterial, antidepressant, antiinflammatory, antispasmodic, anti-toxic, antiviral. Studies have shown that lavender...reduces irritability, apprehension, stress, nervous tension, insomnia, nightmares...



Remember!

Cosmetics Claims Sound Like This...

My fine lines appear... My skin looks... Feels healthier... Feels more hydrated... Eyes appear brighter... I love my skin... Feel more confident...



While Avoiding Claims like...



Common Indie Brand *Claims* **Mistakes**

"We can always just take the claims off our website."

Using claims derived from previous version of a formula

Lack of clinical data to support science of the claim, i.e. wetness protection

Claims derived without substantiation or without statistically relevant panel

Influencer disclosures





"Your products are mind blowing fast and effective. That's the only other way to describe them. If you find a way to make your products better, you are some sort of wizard or genius. They help heal and provide therapy. The bar soaps can handle everything from a fussy baby with purple haze to years of suffering from psoriasis with shea honey oat. On behalf of our customers, thank you."

Jesse Gonzales Oasis, A CBD Wellness Shop Brownsville, TX

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WHAT ARE THE BEST PRACTICES FOR CREATING STAND-OUT CLAIMS?



Defining Claims Testing

Clinical Testing



- Safety testing
- Efficacy and claims substantiation testing – specific to the benefit tested, i.e. increase in hydration
- Conducted in a scientific lab using set scientific procedures and measurement
- Average panel size: 25 to 50
- Governed by regulations



Consumer Testing



- Products that are safety and stability tested/approved for in-market commercialization
- Efficacy and claims substantiation from a panel of women with concerns mapped to the product benefits
- In home use with specific usage instructions
- Reveals emotional connections to products and brand
- Average panel size: 100 to 150

Not all Claims are Created Equal

They Find Consumer Claims Most Compelling

When shown consumer and clinical claims from actual print advertisements touting the same product benefits, respondents stated the consumer claim was more compelling than the clinical claim for the same product.

Consumer Claim	Clinical Claim
82%	18%
81%	19%
75%	25%
69%	31%
69%	31%
68%	32%
66%	34%
65%	35%
61%	39%
61%	39%
	Claim 82% 81% 75% 69% 69% 68% 68% 66% 65% 61%



Clinical vs. Consumer Claims Showdown

When considering the purchase of the following products, which statement, per product, is the most compelling to you?

Taken from real magazine and online advertisements



* In a study of 1,044 US beauty buying women conducted in June 2016.

Clinical vs. Consumer Claims Showdown

When considering the purchase of the following products, which statement, per product, is the most compelling to you?

Taken from real magazine and online advertisements



Firming Claims

* In a study of 1,044 US beauty buying women conducted in June 2016.

Consumer & Clinical Testing = *Powerhouse*



- Leverage your investment in clinical testing to *propel* your consumer claims
- What will give my brand the strongest claims. Set the budget to this!
- Involve the PD team
- What is important to the consumer?
- How strong are your clinical claims?
 Capitalize on the opportunity to make them stronger with consumer testing.
- Use consumer claims testing to bolster your clinical results.
- Carefully consider the timeline
- Involve the marketing department

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Claims Substantiation D0's

TEST YOUR PRODUCTS WITH YOUR TARGET CONSUMER AND GET VALUABLE FEEDBACK

It is an opportunity to make things good (and then better) and right (and then fantastic) for the men and women who use the products.

- Use a reputable research firm with proven methodology
- Involve the PD/Marketing/Regulatory/Legal team
- Test your differentiator
- Find the emotional connection for your consumer
- Bolster your clinical results
- Legal consent
- Carefully consider the timeline
- Know the laws
- Plan for success or setbacks
- Certify and validate claims
Beauty Product Testing Don'ts

- Ignore the laws and put your brand in a position to defend what the government may deem "false claims"
- Bypass legal/PD/Marketing
- Have too few or the **wrong testers**
- Forget the consent forms
- Skimp on the product
- Wait too long
- o Rush!
- Combine claims
- Use 'no-no' words





APPROVED

Types of Products Tested

Cosmetics and Nails

Foundation, Bronzer, Lipstick, Lip Gloss, Nail Polish



Skincare

Acne, Sunscreen, Anti-Aging Skincare, Lotion



Beauty and Personal Care Devices

Anti-Aging Ultra-Sound Devices, Purifying Shower Heads



Body Care Body Oil, Body Lotion, Neck Cream



Hair Care Shampoo, Conditioner, Gel, Styling Cream



Fragrance Perfume, Eau de Toilette, Body Lotion



Men's Care Deodorant, Shave Creams, Beard Balm, Lip Care



Types of *Beauty & Personal Care* **Product Testing** (Consumer In-Home Use Testing)

As varied as your marketing & PD needs

- ✓ Branded
- ✓ Blind
- ✓ Prototype/Pilot
- ✓ New SKU
- ✓ New Formulation
- ✓ New Formulation vs. Old
- ✓ Formula A vs. B for maximum efficacy
- ✓ Old SKU
- ✓ New Set
- ✓ Competitive
- ✓ Fragrance Preference
- ✓ Usage instruction efficacy
- ✓ Advertising compliance







Target Your Testers

Leverage your testing initiatives to create brand evangelists and future buyers.

- Geographic Location
- Shopping Habits
- Skin Concerns
 - o Age
- o Ethnicity
- Household Income
- o Values

Benefits:

- Consumer insights
- Turn browsers into buyers
- Information on price elasticity
- Likelihood of purchase
- Retail strategy validation

Beauty Product Testing Methodology

Independent Voice • Consumer Intelligence • Market Tracking Market Claims • Benchmarked Data



HOW DO YOU USE CONSUMER RESEARCH TO DRIVE CONSUMER DEMAND?



Validate the Claims & Gather Testimonials



DRUNK ELEPHANT



My skin is noticeably tighter, reducing the laugh lines extending from the edges of my lips to my nose. I thought only surgery could fix those. Also made the lines between my eyes much less noticeable. I've tried many serums, including some very expensive brands. None of them are even close to being as effective as TLC Framboos. I also love the packaging. It makes it very easy to get the same amount every time I use it without risking contaminating the product. —Donna B., Henrietta, TX



"At first, I thought the straightener wouldn't work for me since there are no heat adjustments. I thought it may not get hot enough. I have thick hair and it can be hard to style. This was not the case! It worked PERFECT for me and I love the overall results. I currently own a another straightener, but I LOVE this styler so much better. It is gentle on my hair, glides effortlessly, and my hair looks shiny and smooth. Overall, I would absolutely prefer this styler over any other straightener I have used in the past." —*Amber W., St. Augustine, FL*





After 3 uses, 93% said it created a brighter complexion

Algenist ELEVATE Firming & Lifting Contouring Eye Cream



After 10 days of use, 95% of subjects reported visible improvements of skin texture around the eyes

GLAMGLOW FLASHMUD Brightening Treatment

Claims Support in Product Packaging

ADVANCED GENE SCIENCE. VISIBLE SKIN RESULTS

Clinically-advanced anti-aging face treatment backed by 8 years of university and scientific research

- Visibly softens fine lines and deeper wrinkles.
- Reinforces and restores elasticity and firmness
- Hydrates and protects against moisture loss



- Unprecedented results*:
- 100% aaree skin is soothed and nourished
- 100% agree skin is smooth 95% agree skin is healthy and restored

RESVOLOGY

ADVANCED GENE SCIENCE. VISIBLE SKIN RESULTS

Luxuriously hydrating and rejuvenating eye cream with clinically-proven anti-aging actions

- · Minimizes crow's feet, fine lines and wrinkles.
- Reinforces skin firmness and elasticity
- Deflates puffiness and brightens dark circles.



100% agree fine lines and

- wrinkles are minimized
- 100% agree eve area is firm
- 100% agree eye area is hydrated.

Pore Corrector Anti-Aging Primer

This anti-aging primer is formulated with Alguronic Acid and an additional 7 powerful ingredients to visibly refine pores, blur fine lines and imperfections, and improve skin. texture and tone over time. This lightweight, aqueous formula evenly distributes onto the skin, creating a satin-soft finish for smooth, long-fasting makeup application.

After immediate use:

Leaves the skin soft and smooth in 93%* of subjects.

Improves makeup application and wear in 90%* of subjects.

Within 10 days of use:

Blurs fine lines and imperfections in 93%* of subjects.

Visibly improves the appearance of pores in 90%* of subjects.

Directions for Use: Apply evenly to clean and/or moisturized skin, avoiding the eye area. For a flawless finish, allow product to dry prior to applying makeup. Use only as directed.

* Revolts obtained using product once daily before applying Average result measured following an in vitro test with Algurovic Acid (0.151**, 0.04%***) makeup following self-assessments of 100 women.

StriVectin







ALGENIST

Regenerative Anti-Aging Moisturizer

Formulated with Alguronic Acid, the Regenerative Anti-Aging Moisturizer nourishes and restores skin moisture while rebuilding firmness and elasticity. The appearance of wrinkles, fine lines, and pores is minimized. The skin is regenerated.

Within 10 days of use:

Skin moisture is restored in 96%* of subjects. Skin is regenerated in 96%* of subjects. Within 4 weeks of use: Fine lines & wrinkles are minimized in 90%* of subjects. Skin firmness is rebuilt in 88%* of subjects.

Directions for use: Apply to the entire face, neck, and chest area twice a day. Use only as directed.

* Results obtained using product twice daily, following a self-assessment of 100 women.



Soin correcteur anti-cernes

4 to 12 WEEKS / 4 & 12 SEMAINES · Reduces the intensity of dark circles and fades spots/

Réduit l'intensité des cemes et atténue les tâches de peau

StriVectin-EV" 7% PRA 1981 - Wearsin G. Actions 77

Otowaste

C 15 ml/0.5 floz

 100°

100%

Agree eye area is hydrated

Experienced smoother skin

Agree eye cream increases skin

texture

elasticity

Claims Support in Social Media



t1 Retweet *** More

and it repairs dry patches. mioskincare.co.uk/the-activist.h...

· If angroves skin texture

skin feels healthy and fit

#fitskinforlife

Expand

It report dry patches

#mtskinforitio

Claims Support in POS Displays











Claims Support in Print Advertising

WANT YOUNGER, HEALTHIER LOOKING SKIN?

SKINSORIALS" SKINCARE

An exquisite beauty ritual filled with what your skin craves: gorgeous textures, naturally derived scents and effective ingredients.



¹/PURIFY

bareMinerals Cleansers

deliver exceptionally pure and revitalized skin.*

SKINLONGEVITY

²/EMPOWER

is clinically proven to improve skin's overall appearance.**

³/MOISTURIZE

bareMinerals Moisturizers

100% of women experienced an immediate improvement in skin hydration.***

"Based on 1-week independent US consumer studies of 100 to 110 women "Based on an 8-week independent US clinical study of 63 women ""Based on 4-week independent US clinical studies of 37 to 42 women

BE ORIGINAL. BE NATURAL. BE GOOD.

Come in for a personalized consultation and discover how NEW SKINSORIALS unleashes your skin's most vibrantly healthy looking glow.







BETTER FIRMNESS BETTER HYDRATION



THE NEW RESURGENCE AGE-DIFFUSING FIRMING MASK

PLUMPS TO EASE UNES AND WRITINGES
FirmG/ Dr. Murad's latest youth building innovation, tightens
and lifts while dain-plumping Brazilian Fruit Extracts promote
relayers enduction.



PBEE Instructing East Droom (D14 OZ) and Relacensiting URL for Alex and Deceleral (D20) with Age-Diffusing Printing Have purchase. Visit Mandomrephil or sat XEELETINGS is share your meaned focusion of the automation (D20).

Available at Sagesta URA. Managa Druy Spa, Pita Spac and Salema & Manakuum at tus calleg \$60.0071628.



Claims Support in Marketing Materials

EXCLUSIVELY ON STRIVECTIN.COM

DARK CIRCLES

New! Get Even Dark Circle Corrector

\$59 add to beg +

Fades all dark circles. Brightens the use area. New Get Even Dark Circle Corrector has a lightweight, non-greasy testore that's instemily absorbed by deficate skin in the eye area to brighten complexion and reduce the look of under-eye dark circles. Within 4 weeks, sun and dark spots visibly field.

POWERED BY NA-114*

Waken a refreshed, renewed look.

Gal Even Dark Circle Corrector senews, rehydrates and soothes as it deeply nourishes skin. Under-eye area looks less pully, more radiant and translucent so you start the day fresh and youthful tooking.





90% of women see visibly lighter dark circle in only two weeks.

Targets dark circles caused by excess pigmentation, aging or thinning skin

 Fades dark spots and brightens under-eye area

 Helps rebuild skin's moleture barrier and fight off the key visible signs of aging with our patiented, eccentifically-proven NIA-114TM molecule

What makes our new dark circle corrector so different?

 Breakthrough formula features proprietary NIA-114" molecule that boosts the efficacy of Vitamin C Actives*" to brighten the akin

 Specially developed to target all types of under-eye circles that result from aging, hereditary factors or broken capiliarise

 Improves overall health of skin around the eyes to prevent and correct all visible signs of sging



Genius Ultimate Anti-Aging Cream Consumer Study Results

Results obtained following a consumer use study of 100 women using the product twice daily.

95%

Dull skin is

days

brighter in 10

Fragile skin texture appears reinforced within

ALGENIST

opears firmer d within resilie bound suppl

Skin appears firmer and more resilient, and bounce and suppleness appears restored within 28 days Forehead wrinkles, creases and lines are visibly minimized within 28 days

7 out of 10 Women Said Lashes Appeared Fuller.*

Wouldn't you like to be able to say that? Here's what else women told us after using Mary Kay® Lash & Brow Building Serum® once a day for one month during an independent study:







Claims Support in Top Media





FTC Warning Letters

What the FTC is looking for:

- False advertising
- Misleading claims
- Failure to disclose paid endorsements
- Mislabeling
- Drug claims
- Implied claims
- CBD Claims

Recent FTC warning letters:

- Review of websites
- Review of retailing sites
- Review of social media hosted by brand
- Labeling
- Reviews posted on brand's website

Understanding **FDA** Cosmetic VS. Drug Claims

Example

dōTERRA International, LLC Attn: David Stirling 389 South 1300 West Pleasant Grove, Utah 84062 "...are promoted for conditions that cause them to be drugs. The therapeutic claims establish that these products are drugs because they are intended for the use in a cure, mitigation or prevention of a disease."

Dear Mr. Stirling:

Athlete's foot * Herpes Simplex * Infection * Viral Infections * Measles

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed websites and social media accounts (e.g. www.anytimeessentials.com, Facebook, Twitter, Pinterest, YouTube) used to promote your dōTERRA Essential Oil products in August 2014. Based on our review, FDA has determined that several of your dōTERRA Essential Oil products including, but not limited to, "Melaleuca," "Oregano," "On Guard," "Clove," "Eucalyptus," "Frankincense," "Geranium," "Lavender," "Lemongrass," "Myrrh," "Peppermint," "Rosemary," "Wintergreen," "Clary Sage," and "Vetiver" are promoted for conditions that cause them to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The intended use of a product may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution, 21 C.F.R. § 201.128. As described below, the marketing of your dōTERRA Essential Oil products with drug claims and without FDA approved-applications is in violation the Act.

Under the heading, "Fight Your Virus with Essential Oils":

• "Melaleuca: Melaleuca (also known as tea tree oil) has been clinically shown to inhibit the replication of the influenza virus. Some of melaleuca's primary uses include . . . athlete's foot . . . canker sores, chicken pox, cold sore, colds, flu, fungal infections, Herpes simplex, MRSA, shingles, warts and viral infections."

• "Oregano: Oregano is effective in inactivating MNV (non-enveloped murine norovirus) within 1 hour of exposure. Some of the primary uses for oregano include athlete's foot, candida, canker sores, Ebola virus, intestinal parasites, MRSA, ringworm, staph infection, viral infections, warts, and whooping cough."

• "On Guard: On Guard is a blend of doTERRA oils and it has been lab tested to decrease symptoms of the flu. Some of the primary uses of On Guard include antiviral, cold sores, colds, flu . . . infection, lupus, MRSA, pneumonia . . . and warts."

• "Clove: Clove has been investigated on Herpes simplex and hepatitis C viruses and was found to be antiviral. Some of the primary uses of clove essential oil include candida, herpes simplex, lupus . . . viral infections, and warts."

• "Eucalyptus: Eucalyptus has demonstrated an ability to inhibit the Herpes simplex virus. Some of the primary uses for eucalyptus include Influenza, Measles, Neuralgia, Neuritis, Pneumonia, respiratory viruses rhinitis, shingles, sinusitis and tuberculosis."

Class Action



- Sold as a premium brand
- Product sold as "all natural"
- Ingredients included synthetics

August 2016: A <u>class-action lawsuit</u> was filed against Derma E[®] for allegedly misleadingly marketing its skincare products – including lotions, scrubs, and cleansers

DERMA E is proud to be one of the most prestigious clean beauty brands, with a longstanding commitment to our high eco-ethical standards. Over the years we've introduced many extraordinary clean beauty products, each one rooted in our belief that skin health can be visibly improved through the right combination of potent vitamins, wholesome nutrients and exceptional ingredients.Today we've grown to become one of the largest *natural facial care brands* in the U.S.

Purified Water, Glycolic Acid, Glycerin (Vegetable Derived), Caprylic/Capric Triglyceride (Plant Derived), Stearic Acid (Vegetable Derived), Cetyl Alcohol (Plant Derived), Organic Simmondsia Chinensis (Jojoba) Seed Oil*, Glyceryl Stearate (Vegetable Derived), Glyceryl Stearate Citrate (Vegetable Derived), Polysorbate 60, Stearyl Alcohol (Plant Derived), Lactic Acid, Organic Camellia Sinensis (Green Tea) Leaf Extract*, Sodium Ascorbyl Phosphate (Vitamin C, Stay-C® 50), Cetearyl Glucoside (Plant Derived), Xanthan Gum, Dimethicone, Potassium Sorbate, Phenoxyethanol, Ethylhexylglycerin.

The Issue

FDA has not **defined** the term "**natural**" and has not established a regulatory **definition** for this term in **cosmetic** labeling. **FDA** also does not have regulations for the term "**organic**" for **cosmetics**.



Synthetic Ingredients

- Glycerin
- Cetyl Alcohol
- Glyceryl Stearate
- Tocopheryl Acetate

FDA

- Polysorbate 20
- Xanthan Gum
- Dimethicone
- Phenoxyethanol
- Ethylexylglycerin
- Potassium Sorbate
- Zinc Oxide
- Titanium Dioxide
- Glyceryl Stearate Citrate
- Glyceryl Stearate
- Stearyl Alcohol
- Cetearyl Alcohol
- Decyl Glucoside
- Coco-Glucoside
- Cocamidopropyl Betaine
- Sodium Benzoate
- Glycolic Acid

Mitigating the Risk

We will elect to formulate with a **synthetic ingredient** if the natural alternative proves either unstable or animal-derived.

DERMA E products are designed to be completely effective, completely vegan and completely delightful. Our formulas are made with a high percentage of natural ingredients carefully selected and sourced from quality, conscientious origins. We will elect to formulate with a synthetic ingredient if the natural alternative proves either to be unstable or animal-derived. Additionally, to maintain product integrity, we formulate with mild stabilizing systems that may be synthetic in nature. DERMA E does use certified organic ingredients when possible.

CLEAN FORMULAS

Our 100% vegan, cruelty-free formulas also do not contain parabens, sodium lauryl sulfates, petrolatum, mineral oil or artificial colors.



Case dismissed as parties settled.



QUALITY INGREDIENTS

Part of our core ethos is being completely transparent about the ingredients we use. We are proud to state all of the ingredients included in our products on all of our packaging and individual product pages.

We are also happy to provide a comprehensive list of all the ingredients we formulate with below.

Class Action

July 2017: A <u>class-action lawsuit</u> was filed against Philosophy, Inc. regarding the marketing of its "Ultimate Miracle Worker" products



This Philosophy night cream comes in a 50ml glass jar, with a separate sachet of serum pearls. To activate the moisturiser, the pearls need to be combined with the cream until they have fully melted. The formula is designed to target all major signs of ageing, including lines, wrinkles, firmness and texture. With extracts of green tea, coffee beans, orange peel and angelica root, the ingredients work to improve skin regeneration, rebuild its natural collagen and rejuvenate the appearance of the skin.

The Issue

2. The Products are **marketed as drugs**. Drugs are held to a higher standard than cosmetics, requiring pre-approval from the FDA and their represented benefits usually must be supported by randomized, placebo controlled, double-blind clinical trials. Further, the label claims, including represented product benefits, must be truthful and not misleading. On the front of each and every Ultimate Miracle Worker Product package, where consumers cannot miss it, Defendants represent that the Products are "multi-rejuvenating". Defendants affirmatively represent on every Product package that the Products work "from the inside out" to "help your skin rebuild its natural collagen" and help your skin "naturally rejuvenate itself '. The ultimate miracle worker multi-rejuvenating cream and ultimate miracle worker multirejuvenating lightweight emulsion packages further represent that the products contain "dermatologically proven skin rejuvenators." And, the ultimate miracle worker night multi-rejuvenating nighttime serum-in-cream also represents it is proven to improve "skin regeneration and epidermal repair while helping skin rebuild its natural collagen and rejuvenate its appearance layer by layer" (collectively, the "rejuvenation, regeneration, repair and collagen rebuilding representations" or "unlawful representations"). The rejuvenation, regeneration, repair and collagen rebuilding representations are drug claims.

Mitigating Risk

Virtually erases the <u>look of</u> fine lines while you sleep

In 1 week, complexion <u>looks</u> brighter, healthier and more even

In 2 weeks, <u>reduces the look of fine</u> lines and smoothes out the <u>appearance</u> of wrinkles

Over time: Skin <u>looks</u> more and more youthful each morning

*8-week self-assessment study with 48 women aged 27-75, 1 x day usage

WHAT IT DOES

our overnight cream helps virtually erase the look of fine lines as you sleep, while recharging skin and helping counteract the signs of stress on your skin. a powerhouse wrinkle-fighting complex of peptides, hyaluronic acid, indian gentian extract and potent forms of vitamin c an innovative complex of saponins and enhanced hyaluronic acid to help counteract stress-induced damage on skin.

in 1 week: complexion looks brighter, healthier and more even* in 2 weeks: reduces the look of fine lines and smoothes out the appearance of wrinkles* over time: skin looks more and more youthful each morning*

*8-week self-assessment study with 48 women aged 37-75, 1x per day usage

Parties reached a settlement. Case was dismissed.

TBC Conducts Research For Top Brands



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