

The Crazy World of Skincare Claims



VALIDATED
CLAIM SUPPORT

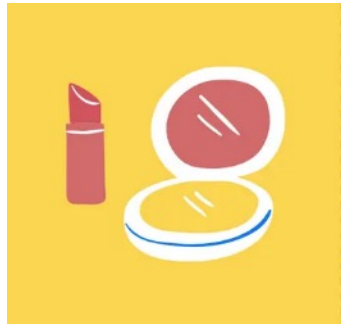


A Quick Introduction

- **Brian Ecclefield**
 - **NYSCC Supplier's Day 2009**
 - 6 years in clinical sales
 - 3 years in clinical development
 - 6 years building Validated Claim Support
-
- VCS – FDA Registered & Inspected
 - Technology Focused
 - 21 Team members focused entirely on custom efficacy studies at the in vivo level



Is it a Cosmetic, a Drug, or Both (or is it a Soap?)



FDA Cosmetic and Drug Refresher

- **How does the law define a cosmetic?**
- **Intended Use**
- The [Federal Food, Drug, and Cosmetic Act](#) (FD&C Act)



FDA Cosmetic and Drug Refresher

How does the law define a drug?

How can a product be both a cosmetic and a Drug?

What about a Soap?

- the bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the product's detergent properties are due to the alkali-fatty acid compounds, and
- the product is labeled, sold, and represented solely as soap [[21 CFR 701.20](#)].



FDA Cosmetic and Drug Refresher

How is a product's intended use established?

- Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials.
- Certain claims may cause a product to be considered a drug.
 - restore hair growth, reduce cellulite, treat varicose veins, increase or decrease the production of melanin (pigment) in the skin, or regenerate cells.
- Consumer perception
- Ingredients that cause a product to be considered a drug



Skincare Claims in the Wild

On Pack “Front and Center” Claims Displayed

Additional drug claims on label

Implied Claims

Sunscreen Labeling According to 2011 Final Rule

If used as directed with other sun protection measures, this product reduces the risk of skin cancer and early skin aging, as well as helps prevent sunburn.

Only products labeled with both “Broad Spectrum” AND SPF15 or higher have been shown to provide all these benefits.



Drug Facts

Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octyl methoxycinnamate 7.5%	Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive ingredients

aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octadecene/MA copolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E), triethanolamine, water

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-XXX-XXXX

Personal Care Testing Overview

Analytical (Product/Ingredient Properties)

Stability
Container Compatibility
Compound Analysis
Ingredient Verification
Certificate of Analysis



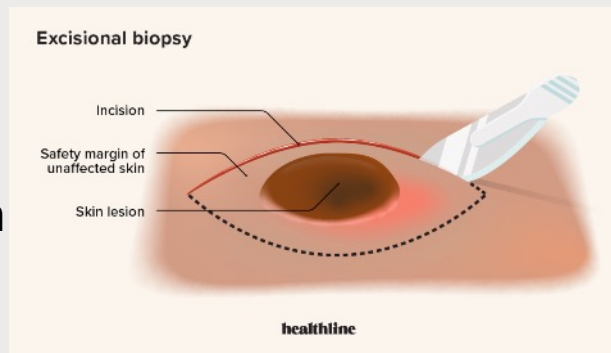
In Vitro (no human contact)

SPF/UVA
Microbiological Testing
Cytotoxicity/Mutagenicity
“Vitro Skin” Model Irritation
Oxidative Stress



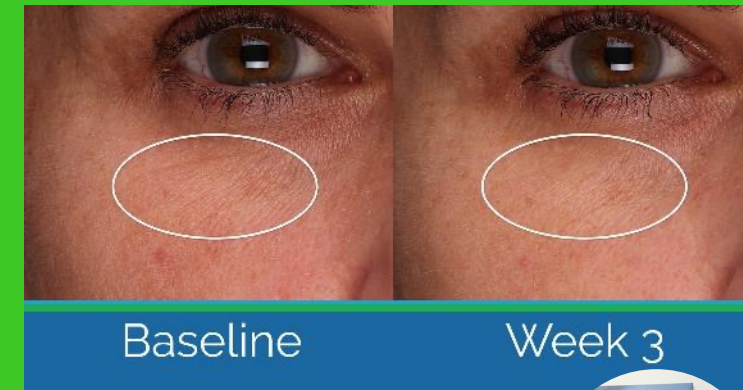
Ex Vivo (On samples collected from Human Participants)

SPF/UVA
Microbiological Testing
Cytotoxicity/Mutagenicity
“Vitro Skin” Model Irritation
Oxidative Stress



In Vivo (On human participants)

Topical Safety
Safety In Use
Clinical Efficacy
Consumer Perception



In Vivo + Ex Vivo Testing Breakdown



Safety (still leads to claims)

RIPT/Patch/Cumulative Irritation
Hypoallergenic, Non-Sensitizing, Non-Irritating, Dermatologist Tested, Dermatologist Approved
Ocular Irritation and Ophthalmologist Safety In Use
Gynecologist Approved
Compound Analysis
Ingredient Verification
Certificate of Analysis

Consumer Perception

Focus Groups

Reactions to Marketing Materials
Design Review
A/B Testing
Subjective Branding Responses
General Feelings
At Home Qualitative Questionnaires (performance)
How does someone "Feel" about a particular Product

Clinical Efficacy

Biophysical Instrumentation
Microbiome



To | 6897 px T1 | 8 px
99.88% Reduction



Cheap and Effective Safety Claims

HRIPT Test Procedure

One test can, in theory, provide a lot of claims
(and hopefully be MoCRA friendly too!)

Human Repeat Insult Patch Testing

Different labs will give you different
“recommendations”

Hypoallergenic, Dermatologist Tested, Not a
Primary Irritant for the Skin, Non-Sensitizing,
Non-Irritating.

Safe for Sensitive Skin



Reasons for Supporting Claims

Sales:

- Product Differentiation
- Unlocking Marketing Language
- Science Driven Skincare
- Consumer Seekout Certain Language ONLY

Regulatory:

- Certain Language unlocks “Drug Vibes”
- “Sufficient Data” to Support Claims

Legal:

- Competitive Law Suits
- Consumer Class Actions
- Direct Secondary Challenges from Industry
- Awareness Groups



What Constitutes a Validated Claim?

Regulatory:

FDA or other international Monographs
Best Practices
Industry Standards

Competitive Landscape:

Certain Language unlocks “Drug Vibes”
“Sufficient Data” to Support Claims

Consumer Comfort:

Best Practices:

Reasonable and/or sufficient scientific data to
backup a claim



OTC Level Claims “Regulatory and Recommendations”

Acne OTC Implications

Drugs are dictated by 2 different aspects:

Active Ingredients –

There are plenty of natural ingredients out there that are clinically proven to reduce sebum production and inflammation. . .

In order to say “Acne” on your product – you must pass the 2 part test

“Secondary Claims” would include redness reduction, oil control, and “helps with troubled skin”



OTC Level Claims “Regulatory and Recommendations”

Sunscreen OTC Implications

Drugs are dictated by 2 different aspects:

Active Ingredients:

Label Claims

In order to say “Acne, Pimple, Lesion, or Whitehead” anywhere on your product you must have an OTC ingredient AND substantiate “reasonable” proof of efficacy

There are plenty of natural ingredients out there that are clinically proven to reduce sebum production and inflammation. . .

In order to say “Acne” on your product – you must pass the 2 part test

“Secondary Claims” would include redness reduction, oil control, and “helps with troubled skin”



4 Pillars of In Vivo Efficacy

Subjective Perception

20-25 questions per timepoint

Wide swathe – can hit hydration, anti aging, redness, smoothness, suppleness

Not technically “clinical”

79% of women **agree** that their skin felt more smooth

CANNOT say 79% more smooth.

No.	Question	Agree	Disagree		
1	The test product improves skin clarity, leaving a healthy, even tone.				
2	The test product reduces the appearance crow’s feet around the eyes.				
3	The test product improves skin’s overall appearance.				
4	The test product reduces the appearance of fine lines and wrinkles.				
6	My jawline appears more defined since using the test product.				
7	My face appears more youthful since using the test product.				
8	My skin feels firmer since using the test product.				
9	The test product makes my face look:				
	< 5 Years Younger	5 Years Younger	10 Years Younger	15 Years Younger	>15 Years Younger



4 Pillars of In Vivo Efficacy

Expert Clinical Grading

Clinical Setting

Professional or at home applications

controlled Temp/Humidity for Consistency with standardization

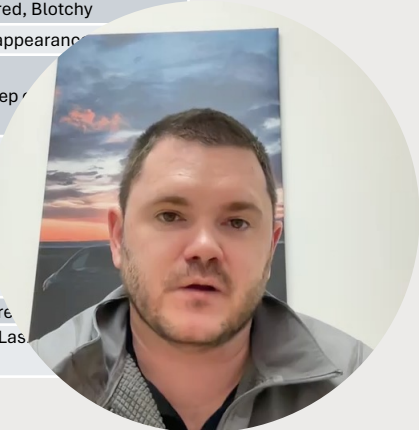
Trained Expert Objective Grader
Technician, MD, Aesthetician,
Cosmetologist, CRC, Dermatologist

Claims about statistical significance

Can hit like 5-7 parameters

Don't overdo it though!

Expert Grader Capabilities		
Parameter	Positive Anchor	Negative Anchor
Fine Lines & Wrinkles (Global)	None	Numerous, deep wrinkles
Skin texture smoothness	Smooth, even surface appearance	Rough, uneven surface appearance
Skin texture softness	Smooth, soft surface feel	Rough, coarse surface feel
Firmness	Firm, Tight appearance	Loose appearance
Elasticity	Good stretch and recoil properties	Poor stretch and recoil properties
Suppleness	Pliable, Bouncy, Supple appearance and feel	Rigid, Stiff, appearance and feel
Contours	Plump, full cheek contour	Hollow, concave cheek contour
Plumpness	Filled, smooth, firm appearance	Thin, loose appearance
Neck: Horizontal Lines/Wrinkles	None	Numerous deep lines/wrinkles
Sagging (Mid face)	Taut, "awake"	Sagging, "tired"
Under Eye Bags	None, smooth appearance under eye	Severe, pronounced bags, puffy appearance
Pore Appearance	Small, not easily visible	Large, easily visible
Shine	Matte, velvety appearance	Shiny, slick appearance
Overall Skin Quality/healthy appearance/condition	Vibrant, Healthy appearance	Unhealthy appearance
Brightness/Radiance/ Luminosity	Radiant, Luminous, glowing appearance	Dull/Matte and/or Sallow
Skin Tone Evenness	Even, Healthy skin color	Uneven, Discolored, Blotchy
Skin Tone Clarity	Clear appearance	Mottled, patchy appearance
PIH (post-inflammatory hyperpigmentation)	None	Highly visible, deep
Dark Spots / Age Spots (intensity)	None, no color difference present	Intense / Deep color brown / tan)
Discoloration/ Hyperpigmentation	Uniform, even appearance	Uneven, discolored, pigmentation present
Complexion Health	Even, Healthy Color and Surface Texture, No Blemishes	Blotchy, Uneven, Blemishes
Blackhead Severity	None	Numerous, Severe
Lash Density/Volume	High, Voluminous, Dense Lashes	Low, Slight, Thin Lashes



4 Pillars of In Vivo Efficacy

Biophysical Instrumentation

% based improvements in conditions

Hydrates by up to 143% in as little as one use

Helps protect the skin's natural barrier

Requires clinical visits – cannot be done at home.

“Laser Focused.” 1 Instrument hits 1 claims family



4 Pillars of In Vivo Efficacy

Clinical B/A Imaging

% based improvements in conditions

Possible to run secondary analysis on individual images (Up to XX% improvement) or entire panels.



Cosmetic and Skincare Claims

Sunscreen OTC Implications

Drugs are dictated by 2 different aspects:

Active Ingredients:

Label Claims

In order to say “Acne, Pimple, Lesion, or Whitehead” anywhere on your product you must have an OTC ingredient AND substantiate “reasonable” proof of efficacy

There are plenty of natural ingredients out there that are clinically proven to reduce sebum production and inflammation. . .

In order to say “Acne” on your product – you must pass the 2 part test

“Secondary Claims” would include redness reduction, oil control, and “helps with troubled skin”



How to Build a good Clinical . . . Relationship

- **Tangibles**
 - Timelines, Price, Turn Around Time, Quality of Work
- **Less Tangibles**
 - Customer Service, Saying No, Expertise
- **Faster + Better + Cheaper? No Way**
 - Do your due diligence. Go Search for FDA Current Drug Establishments and make sure the lab is Active
 - Search on Google for Fraud, Search on Glassdoor for employee reviews (often noting fraud!)

Questions . . . Comments?!?!

For more info anytime you can reach out to me:

Brian Ecclefield brian@validatedcs.com



VALIDATED
CLAIM SUPPORT

