

*Pillar #9 Skincare Ingredients, Products, and Treatments*

Today's Agenda:

- Definitions of "cosmetics" and "drugs" in the US, CA, EU
- OTC vs. professional grade vs. medical grade skincare
- Safe language around claims--what ingredients and products can and cannot do
- Claims vs marketing terms
- Discussion and questions!



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Definition of "Cosmetics"

- **According to the US:** Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance.
- **According to Canada:** Any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.



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Definition of "Cosmetics"

- **According to the EU:** Any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.




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Definition of Drugs

- **According to the US.** "Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease...and articles (other than food) intended to affect the structure or any function of the body of man or other animals."
- Over-the-counter (OTC) drugs are drugs that can be purchased without a doctor's prescription.



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Definition of Drugs

- **In Canada:** A Drug is any substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; restoring, correcting or modifying organic functions in human beings or animals; or disinfection in premises in which food is manufactured, prepared or kept.



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Definition of Drugs, and Can It Be Both in The EU?

- **In the EU:** A drug or "medicinal product" is a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.
- The EU recognizes that some products have more than one intended use and fall in both categories. These products are then considered both a cosmetic and an OTC drug, and must comply with the regulatory requirements of both categories.




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Can A Product Be A Cosmetic and A Drug?

- **According to the US.** Some products meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses." For example, a facial cleanser is a cosmetic because its intended use is to cleanse the hair. An anti-acne facial cleanser is a drug because its intended use is to treat acne, and it contains FDA-approved acne drugs as ingredients, such as salicylic acid, sulfur, or benzoyl peroxide. Consequently, an anti-acne cleanser is both a cosmetic and a drug. Among other cosmetic/drug combinations are moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.



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Cosmetic-Drug Interface: Canada

- **Cosmetic-Drug Interface:** Products that may share the characteristics of both "cosmetic" and "drug", as defined in the *Food and Drugs Act*, making them more difficult to classify. Such products may include, for example, acne therapy, anti-perspirants, anti-dandruff products, fluoride-containing anti-caries products, medicated skin products, diaper rash products, antiseptic skin cleansers, sunburn protectants, skin whiteners and tooth whiteners.



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How A Product is Regulated in Any of These Examples Really Boils Down to This:

- What ingredients are in the product?
- What is the intended use of the product?
- **What claims are being made about the intention and efficacy of the product?**

*It's important to note that the US, Canada, and the EU do NOT associate or mention health or wellbeing with their definition of "cosmetics."*




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OTC vs. Professional Grade vs. Medical Grade Skincare

- Many aestheticians and even dermatologists refer to products that are purchased anywhere outside a spa or doctor's office as "OTC"—meaning "over-the-counter."
- This is actually an incorrect usage of the term. A true OTC product either is a drug or skincare product that contains drug ingredients (and is labeled with a Drug Facts section) that is available without a prescription from a licensed medical provider.
- So essentially, if your spa sells an acne cleanser with OTC drug ingredients, you are selling an OTC product.




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What's The Difference Between Products Sold Outside of Spas and Doctor's Offices and Professional or Medical Grade Products?

***NOTHING AT ALL OTHER THAN HOW THE PRODUCT IS MARKETED.***




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Professional and Medical Grade Skincare is A Myth

- The idea that "professional" or "medical" grade skincare products contain higher quality and higher concentrations of "active" ingredients that can only be legally sold by a licensed professional is a lie.
- Most mass-produced skincare products come from labs that use the same stock formulations for all skincare products, regardless of where they are sold. They will make the products with the lowest cost ingredients available, unless the brand specifies differently. MOST DO NOT because they want to keep their costs down.
- This is not the same case with small batch and artisan/herbal makers. *These products are often better quality!*




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Professional and Medical Grade Skincare is A Myth

- Product companies specify that their products are “professional” or “medical” grade to determine how and to whom they are SOLD and can be distributed by. These grades are meaningless in terms of product effectiveness, nor can they only be sold by licensed professionals according to the law.
- It is true that there are different grades of ingredients—food grade, cosmetic grade, pharmaceutical grade. But that doesn’t necessarily mean that one is better than the other. It has more to do with how the ingredients are processed to meet the requirements of how the end-products they are used in will be regulated, or to be more appropriate for that particular product.



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More “Professional” Skincare Myths

- “Professional products contain higher concentrations of active ingredients.” All extracts, actives, performance ingredients, etc have a recommended usage range within a product. It is true that some companies exceed those to claim greater efficacy. This is not necessarily a good thing though, and can be outright dangerous and a liability.
- “Cosmeceuticals are more effective than regular cosmetics.” Nope. The term “cosmeceutical,” is a marketing term and is not recognized by the FDA or any other regulating body as having any meaning in terms of efficacy.



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Safe Language Around Claims

- Stick within the scope of cosmetic/aesthetic terminology
- Don’t make any claims whatsoever that your products or their ingredients can affect or change the structure or function of the skin. *EVEN IF THEY DO and have science behind them.*
- Don’t make any claims whatsoever that your products can affect anything deeper than the epidermis. The dermis is technically outside the scope of cosmetics AND aesthetics, and that *includes claims about collagen and elastin. EVEN IF THEY DO and have science behind them.*




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Safe Language Around Claims--Things Not to Say

- Heals or treats a disease or condition of the skin
- Antibacterial, antiseptic, anti-inflammatory benefits
- Reduces redness, regulates sebum production, heals sunburn, removes scars
- Reduces transepidermal water loss, assists cell turnover rate
- Tyrosinase-inhibitor
- Reverses free radical damage

Makes the skin more resistant to UVA/UVB damage



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Safe Language Around Claims--Things Not to Say (EU-specific)

- No free-from claims
- No claims about how the product performs/efficacy
- No claims that a product does not contain ingredients that other similar products may contain that implies it is better
- No drug/health/medicinal claims
- No "hypoallergenic" claims
- No "not tested on animals" claims



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What About Anti-Aging/Ageing Claims?

- Technically in the US/CA, anti-aging/anti-ageing are not legal claims
- Products intended to affect the structure or function of the body, such as the skin, are drugs, or sometimes medical devices, even if they affect the appearance. So, if a product is intended, for example, to remove wrinkles or increase the skin's production of collagen, it's a drug or a medical device.
- The EU, however, DOES allow the "anti-ageing" term




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But What About ALL The Brands That Make These Claims?

- Until very recently, the skincare industry has been mostly unregulated
- Over the past several years, the FDA and FTC (and equivalent agencies in other countries) are paying closer attention to claims because drug/health claims would require testing and approval (which they make money from). New legislation for more stringent regulation is in the works.
- Huge companies with vested interest are less likely to get "busted" because many of their products do contain approved drug ingredients and can afford the approval process. But even if they do—they can afford the fines.



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But What About ALL The Brands That Make These Claims?

- Mid-to-small companies are actually a greater target because they usually cannot afford the testing and approval process, so they have to be extremely careful. They cannot afford the fines. Most "busts" happen from unsafe language in online content.
- Aestheticians, cosmetologists, and other skin wellness practitioners who sell products that make these claims however DO have to be careful about claims to stay within scope.
- An aesthetician selling an acne cleanser claiming to a client that the product will heal their acne is out of scope. An aesthetician who uses a medical device and claims that the treatment boosts collagen production is out of scope.



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Questions and Discussion




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