

Cosmetics: General Concepts & Regultions

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PhD in Cosmetic Science

لما فكي علم مستحضرات التجميل
لديغ انت compounding (خلط / تركيب)
النسب هو علم متعدد التخصصات.

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Cosmetic Science

زغب الأذوية برهنو في مستحضرات التجميل بدنا نفهم التسوية وللاستع
التسوية في مستحضرات التجميل يعود عليه الجزء الأكبر في نشر مستحضرات التجميل وإنتاج المشتري أكثر بكثير من الناحية العلمية.

Marketing & Business

لازم تكون عارف ال Needs للمشتري
مشتات نرلهم المستحضرات المناسب و البعض خلقت الحاجة على سبيل المثال ال Nose Job نرخوا بقتل المراهقين من طريق مواقع التواصل انه لازم اتفهم يكون بشكل معين مشتات يكون حلو و هذا خلف حاجة.

Customer needs

زغب زغب أفي مستحضرات هيلد في النهاية بدو يخلط طول فترة ال shelf life فانظ عليه مشتات هيك لازم تكون فاهم Microbiology

Microbiology

لازم تكون فاهم

Analytical Sciences

لذنه بالنهاية انت بديك قال ونشوف تركيز تركيز المواد في المستحضرات مثلك تتأكد من ثباتية انه ال API فلت ثابتة وهيك.

كمان لازم تكون فاهم Regulations
لذنه اذا بديك تدخل بعالم التسوية والتعبير والتعبير بديك نفهم الأنظمة التي بتحدد عليك ابرخال هاد المستحضرات وبيع وتسجيلات.

Regulations

*** لا يوجد مستحضر خال من المواد الكيميائية

Formulation Technology

بتكسب كيميائي داخل مساقات الصيدلانيات والتعبير

Pharmacology

لازم تكون فاهم
لذنه في مواد بتأثر على البشرة.
يعني لما حد فيكالك هاد جفف للتعبيرات
ديك تكون فاهم ال concept
تبع ال MOA الة وكيف بتشتل

Anatomy & Physiology

مشتات نفهم تشغل المستحضر
لازم تكون فاهم ال Anatomy & physiology
للحوض الي بنحط عليه هاد المستحضر.

Chemistry

مستحضرات التجميل بالنهاية
هي مركبات كيميائية بالتالي
لازم تكون فاهم ال chemistry
* you can study chemistry & enter cosmetics world
AKA "Cosmetics chemist"

Basic definitions

- Cosmetics:

- 'Cosmetic' is derived from the Greek *Kosmesis* (adorning)

إعجاب

Definition of a cosmetic product

- Food and Drug Administration (FDA) ← *بعد 1938، ومن وقتها ما تعدل لا 2022*
- The US Food, Drug and Cosmetic (FDC) Act defines cosmetics as:
 - (1) *مصطلح قانوني* Articles intended to be rubbed, poured, sprinkled or sprayed on, applied to the human body *الانسان* for ***cleansing, ***beautifying, ***promoting attractiveness, or ***altering the appearance.

Basic definitions

Articles أي اقـ يستخدم خففـ مكونات هـاـ د
أيضاً يستخدم خففـ مستحضرات التجميل.

(2) Articles intended for use as a component of any such articles;
except that such term shall not include soap”

- Cosmetics shall not include Soap, like الحلاوة النابلسية

“Soap include only those soaps intended for cleansing the human body, that are labeled, sold and represented solely as soap, and that consist primarily of nonvolatile detergent from an alkali salt of fatty acids”

الصابون النابلسية هـ عبارة عن Alkali salts of P.a
يعف هـ عبارة عن P.a جاعب من الزيت (أعـ قح) أو من
دهون حيوانية بكونها فاعلوه مع اقـ ← alkali Sodium hydroxide / potassium
مشتات تطلع الصابون - بجاعب الالة هـ مسـ Cosmetic
هـ صابون تقليدية.

SOAP according to USFDA

- It cleanses our hands and body → non-cosmetic (traditional soap)
- 1 • Moisturizing and deodorizing → cosmetic
- 2 • Antibacterial, antiperspirant, anti-acne → OTC drug-Cosmetic product

* إذا دخلت على موقع الغذاء والدواء الأردنية
في تعليمات خاصة بالصابون المضاد للبكتيريا.

Basic definitions

- There is a significant difference between cosmetic products and drugs

- Drugs are defined in the FDC Act as:

Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man..... Articles intended to affect the structure or and function of the body.

مستحضرات التجميل ممنوعة تعمل ههنا

The grey area between a drug and a cosmetic product

- ✓ A cosmetic product is not meant to affect the structure or function of the skin

- Nowadays this 'strict' definition is becoming more and more blurred

- In the past nearly all cosmetics were no more than simple moisturizing, cleansing, or colouring products

لكن هذا لا؛ هاروا يدخلوا
على خط انه لا دخل تغيير
هاروا بل Structural Function

- The legal difference between a cosmetic and a Drug is determined by what?

- E.g. Salicylic acid

NSAID / مسكن

- FDA relies on the representation made for the product in its labeling "any display of written, printed, or graphic matter"

- Intended use vs. chemical composition

كيف الغذاء والدواء نتيجة هابي
المنفعة المرادفة بتحدد إذا كان
المنتج Cosmetic ولا Drug ؟

- إذا كان 2٪ وأقل مسموح استخدامات
Cosmetics ولا Cosmetics ويكون من هيفت ال Cosmetics line

They use
for acne
prone skin
instead

- إذا كان ال representation ال Anti - Acne
بالا USA بهيف OTC هيف لو كان > 2٪

بتأخذ شغلتيك بين ال اعتبار
لكا المكون / المواد لك الادعاء (Representation)

The grey area between a drug and a cosmetic product

- Currently, many cosmetic products are marketed with statements such as:

“Accelerates the renewal of cells”

“build up supportive tissue in the skin”

“Repairs sun damage to the skin”

“Repairs skin aging”

- These claims changes in the function and structure of the tissue

“will temporarily improve the appearance ofsigns of aging”

الشركات العالمية
بالنسبة لوضع الادعاء claim
تغير هوية ادعاء قمار بزيادة الادعاء مشاهد ما تتركه
بالادعاء وادعاء ، ففعلت هوية تجا لهاد الادعاء .

10/8/2024

Saja Hamed, Ph.D

كل هاد يتدل انه المنتج
جعل ادعي علاجي الجلد

+

شركات التجميل الي ناعوه
ال Regulation ما تستخدم معها الا
بالضاهف الي عرفت انه ما
فيها هاد ال Regulation الي
تتمنع .

يغير هوية قتل ال label
لنفس المنتج من دولة لأخرى

هوية المستحضر نفس هوية مكتوب
عليه ولا ادعي من الادعاءات بسب من
خلال التأثيرين فبوا هاد الادعاءات

The grey area between a drug and a cosmetic product

بلاد USA ما في افي هيا Drug
يا Cosmetic سبب بالذروت عادي
عنا افي اسمه مستحضر تجميل هيا في

تجميل هيا في

- *Cosmeceutical* is frequently used to describe products that are known to have biological action but which are regulated as cosmetics
- the cosmetic industry uses this word to refer to cosmetic products that have medicinal or drug-like benefits
Have a biological action
مثل ما في افي اسم مستحضر واحد في انما بتسبب جديد خلايا الجلد
- Food, Drug, and Cosmetic Act does not recognize the term "cosmeceutical"

هناك مواقع تساعد نفهم سنو الفرق بين الدوا والمستحضرات التجميلية

- 1 • <https://www.hugheshubbard.com/news/ealert-defending-class-action-claims-of-false-cosmetics-labeling>
- 2 • <https://cen.acs.org/articles/94/i19/Making-cosmetic-claims-stick.html>
- 3 • <https://www.primematterlabs.com/resources/difference-between-cosmetic-and-OTC>



In the US, a product qualifies as a drug when the product is

or function of the body. Drugs can be marketed as OTC if they comply with established OTC monographs established by the FDA, or through the submission of an NDA (New Drug Application) to the FDA ([Learn more: How OTC Drug Products are Approved by the FDA](#)). Examples of OTC drug products include, sunscreen, antidandruff shampoo, acne care, and hand sanitizer.



Examples of Drug Claims

1) Acne Treatment	6) Dandruff Control
2) Anti-inflammatory	7) Eczema, Psoriasis, or Rosacea (Treatment of)
3) Anti-septic, Anti-bacterial, Anti-microbial	8) Hair Growth / Regrowth
4) Antiperspirant	9) Scar Care
5) Chapped/Cracked Lip Treatment	10) SPF / Sunscreen

These designations are not mutually exclusive as a product can be both cosmetic and OTC when it has two or more intended uses. For example, an anti-dandruff shampoo will claim to both *cleanse* hair and *treat* dandruff. Additional examples include makeup with sun protection claims and deodorants that are also antiperspirants. These products must comply with the requirements for both cosmetics and drugs.

the defined amount in a relevant monograph, then the product cannot be marketed as an OTC drug. For example, for a product

acid. If it is less than .5%, then the product may only make cosmetic claims that speak to cosmetic benefits like *exfoliation* or *smoothing*.



Cosmetic Claims

1) Beautifying

2) Cleansing

3) Conditioning

4) Hydrating

5) Moisturizing

The differentiation can be difficult to decipher, and brands need to be mindful of the language used in the marketing of the product. If a product is intended to make lines and wrinkles less noticeable by *moisturizing* the skin (lotion) or *hiding* them (makeup), then it qualifies as a cosmetic claim. But if a product claims to *remove* wrinkles or *increase* the skin's production of collagen, then it would be considered a drug by the FDA.

noticeable by *moisturizing* the skin (lotion) or *hiding* them

collagen, then it would be considered a drug by the FDA.

Subjective Claim
تقريباً معنا كلفه looking هيك صار
هعب تقيست

Drug claim بهير the number of fine
اذا كان مكتوب

Cosmetic Claims	OTC Claims
For thicker and fuller <u>looking</u> hair	Restores hair growth
For a visibly brighter and glowing complexion	<u>Removes</u> dark spots
To achieve suppler, healthier-looking skin	<u>Eliminates</u> cellulite
<u>Reduces</u> the appearance of fine lines	Removes wrinkles
Promotes fuller looking hair	For the treatment of alopecia
Reduces the look of hyperpigmentation and discoloration	Clears up acne scars

موجود بالسوق كثير
شاهدي هانت ومستحضرات
تدعي هاد
للادعاء وهاد كله
علما (منه مشرب انه
بتمونه هو التغليف العلمي
والعناوين للموجود)

Learn more about OTC drug products: [How OTC Drug Products are Approved by the FDA](#)

Prime Matter Labs offers tailored product development and production, adapting and innovating along with your business. Work with our team to capture exactly what it's going to take to meet your consumers' unique needs. Contact your Prime Matter Labs Project Manager or start your project [here](#).

Cosmetic science

While differences exist, both EU and U.S. authorities require **claims substantiation**

	European Union	United States
Enforcement	The European Commission sets cosmetic standards which are enforced by member country regulatory authorities. ✓	The Food & Drug Administration and the Federal Trade Commission both have jurisdiction over cosmetic claims. Individual states have regulatory authority too. ✓
Registration	Cosmetic products must be registered and proof of claims must be filed before they go on the market. ✓	Cosmetic products and ingredients do not need FDA registration, but they can be registered voluntarily. Claims are not filed with the agency. ✓
Truthfulness	Claims must be truthful. i.e. if said to contain honey it must contain honey. ✓	Companies must have competent and reliable evidence to substantiate any ingredient-related claims. ✓
Evidence	Claims should be supported by verifiable evidence. Experimental studies should be reliable and reproducible.	To support performance claims companies need both clinically and statistically significant data.

Sources: European Commission, FDA, FTC

In Europe, both categories are considered cosmetics, and formulators have more

إثبات الادعاء

الغذاء والدواء
+ الأمريكية عندها
أفب اسمها
Post market
Surveillance

يغيب إذا شامت أفب ادعاء
دوافي لشركة تبصيلية
بتقدر تبغها رسالت
تذيرية (تدلي) أو
تجلبية كدواء.

بسم فافينا انه
شوهو ال Evidence
بال San Cosmetics
نقدم على ال In Vivo study
على الخلايا أو دراسة على
عدد قليل من الناس



Making cosmetic claims that stick

SHARE



يعف مثل هذا الادعاء
 بناءً على شو علمت كل
 في عندي Regulation
 بتحكيلك كيف
 تعلقه ؟

كثير من هاذ الادعاءات
 ما في Regulation
 بتحكيلك كيف تعملها

٢
 بتصدق على
 الشركة



Credit: Shutterstock



Cosmetic Labeling Class Actions and Applicable Defenses

The recent volley of warning letters by the FDA has also triggered a wave of follow-on class action lawsuits against cosmetic manufacturers in general, including manufacturers not singled out via FDA warning letters. Typically, such class action lawsuits are broader in scope than the FDA warning letters, and include claims for false or misleading advertising, unjust enrichment, breach of warranty, and state-specific consumer protection law violations. If certified, the cost and potential class-wide damages associated with such class action lawsuits can threaten to overwhelm or even bankrupt the targeted cosmetic manufacturers.

Despite the upswing in these types of class action lawsuits, there is a glimmer of hope. Two recent U.S. Supreme Court decisions (*Comcast Corp. v. Behrend*, - S. Ct. - (March 27, 2013); *Wal-Mart v. Dukes*, 131 S. Ct. 2541 (2011)) are filtering through the U.S. District Courts and providing effective defenses to class certification. These defenses include (1) requiring a rigorous analysis of all prerequisites for class certification under both Rule 23(a) and Rule 23(b)(3) of the Federal Rules of Civil Procedure, (2) requiring an analysis of the merits of the underlying claims whenever they overlap with class certification issues, (3) requiring damages be measurable on a class-wide basis and not necessitate individual damage calculations for each purported class member, and (4) raising the possibility that any expert testimony proffered for class certification purposes be subjected to the heightened scrutiny of a Daubert-style analysis.

في أمثلة على هاب القضاة بالواقع
فنت هاب الفقرة اذا حاسبت
تفهموا الواقع بشكل
أكبر

* ضد الواقع بوضعك انه كثير
بال USA بتفسير قضايا على
ادعاءات False cosmetic claim
يعني استخدمت ادعاءات
علاجية وليس قضاية





Cosmetics

[Home](#) > [Cosmetics](#) > [Labeling](#) > [Labeling Claims](#)

Labeling Claims

["Alcohol Free"](#)

▶ ["Cosmeceutical"](#)

["Cruelty Free"/"Not Tested on Animals"](#)

["Hypoallergenic" Cosmetics](#)

["Organic" Cosmetics](#)

"Cosmeceutical"



SHARE



TWEET



LINKEDIN



PIN IT



EMAIL



PRINT

Consumers and manufacturers sometimes have questions about the term "cosmeceutical."

While the [Federal Food, Drug, and Cosmetic Act](#) (FD&C Act) ^{US FDA} does not recognize the term "cosmeceutical," the cosmetic industry uses this word to refer to cosmetic products that have medicinal or drug-like benefits.

The FD&C Act defines drugs as those products that cure, treat, mitigate or prevent disease or that affect the structure or function of the human body. While drugs are subject to a review and approval process by FDA, cosmetics are not approved by FDA prior to sale. If a product has drug properties, it must be approved as a drug.

Consequences of drug status:

- It is more burdensome and expensive for a product to be classified as a drug rather than a cosmetic
- A “new drug” may not be marketed at all without prior FDA approval
- Cosmetics are not approved by FDA prior to sale.

Definitions of Cosmetics and Directives

USA

- **FDA has** Limited authority
- Legislations remained unchanged since 1938
- MoCRA 2022
Modernization of Cosmetics Regulation Act - **ببساطة غير فعال كاملًا**

EU

- ✓ Continuous updates (1976-2009)
- ✓ Model of modern cosmetic regulations worldwide

ASEAN

- ✓ Cosmetic Directive (ACD) is in force in all 10 ASEAN member countries
- ✓ Modeled after the EU Directive

بشبهه مع إندونيسيا - فتلفت
لكل دولته مثلك إنك تدخل
مستحضراتك على أوروبا أسهل
من إنك تدخله على الصين

USA

- Articles for cleansing, beautifying, promoting attractiveness, or altering the appearance **without affecting structure or function**

EU

- Any substance or mixture placed in contact with external parts or with teeth and oral cavity to clean, perfume, change their appearance, protect, keep them in good condition or correct body odor"
- Allowed to have mild Pharmaceutical activities**

مستحضرات لعلاج البشرة
نظف الشامبو عادي
Cosmetic بسلوه

ASEAN

- Same as EU

Classifications

USA

- 1 • Cosmetics
- 2 • OTC drug-Cosmetic Product
- 3 • Drugs

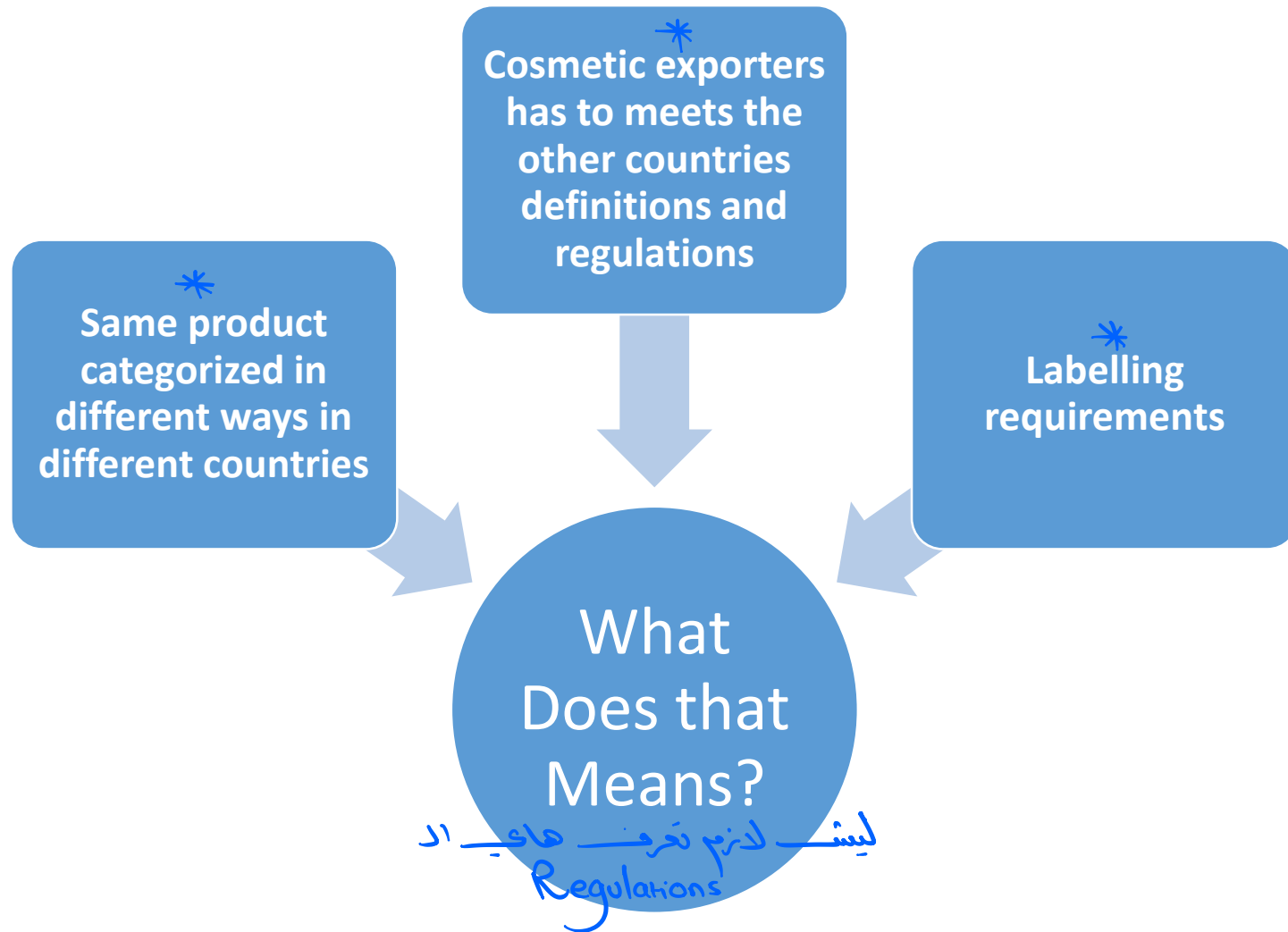
with drug claim ex:
dandruff shampoo

EU

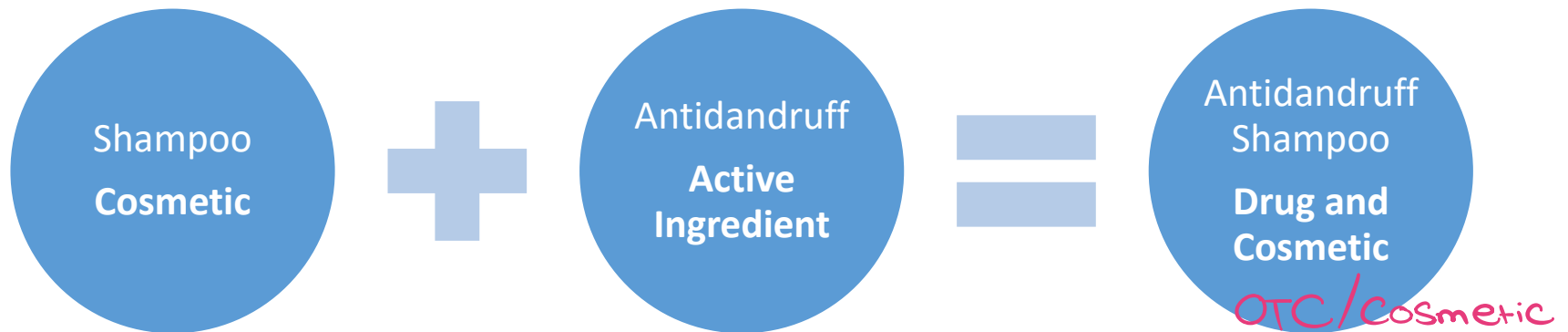
- 1 • Cosmetics
- 2 • Drugs

ASEAN

- **China regulation defines two categories:**
 - Normal cosmetics
 - Special cosmetics *منتجات تفتيح البشرة*
- **Japan regulations defines two categories:**
 - Cosmetics & Special cosmetics
 - Quasi Drug *شبه الدواء* = OTC



examples :
In USA



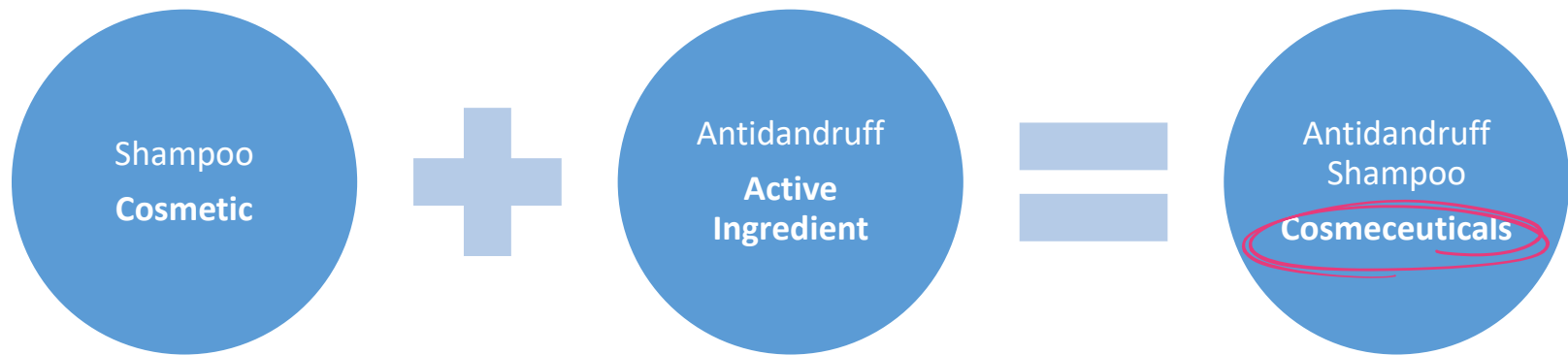
In EU

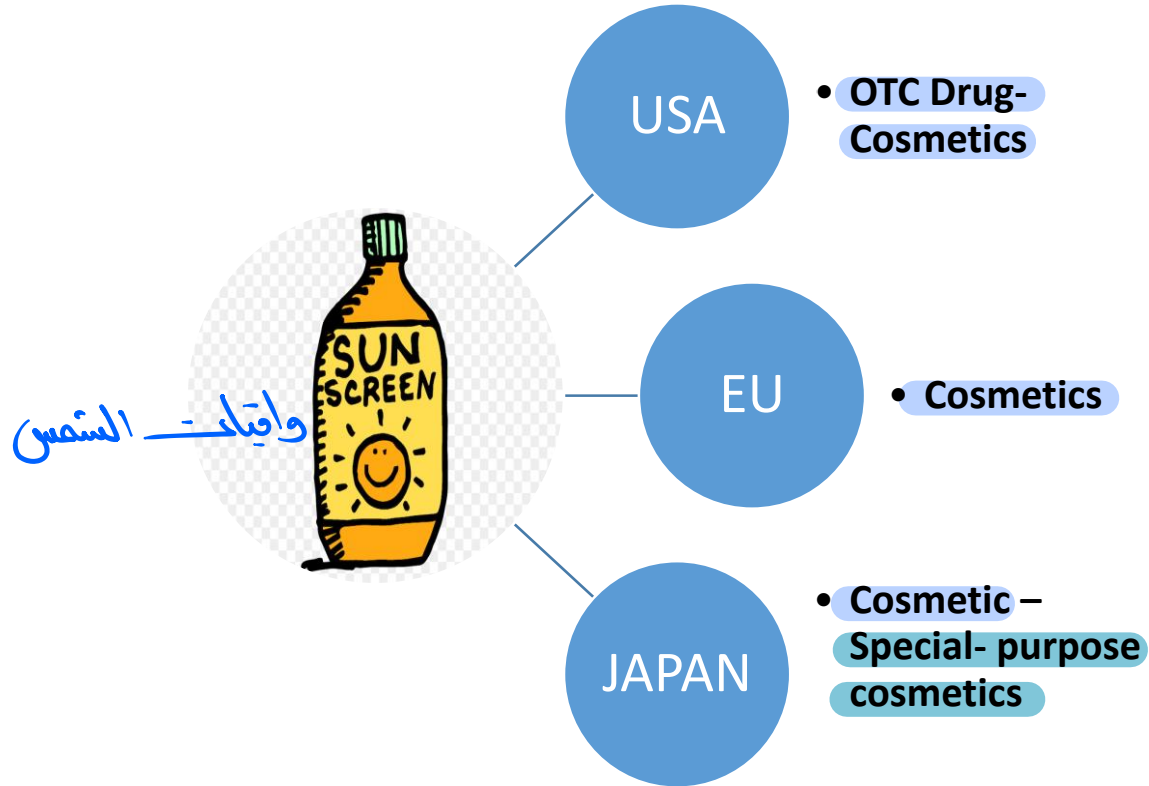


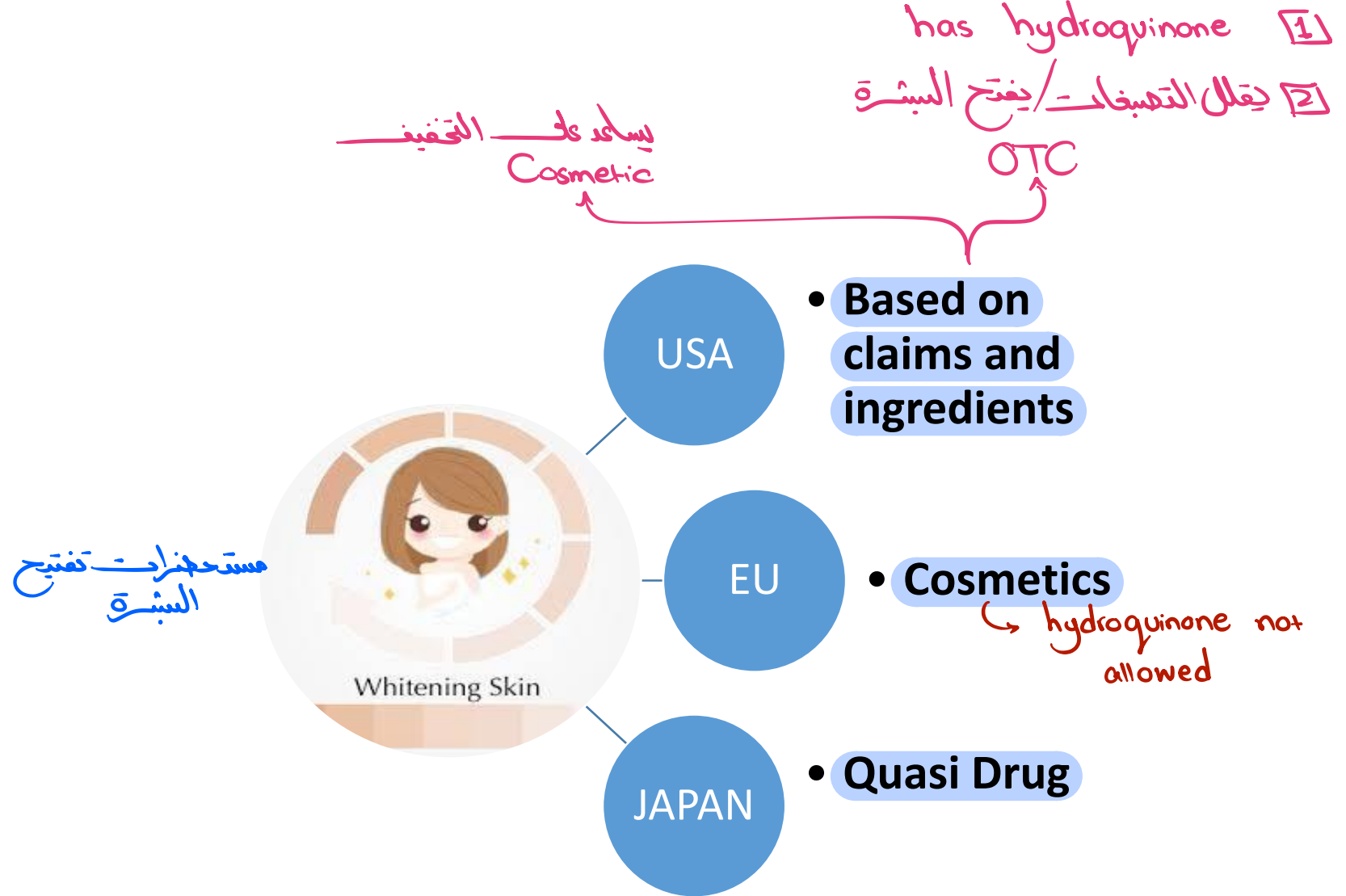
In Japan



In Jordan







Premarket approval

USA

- ✓• Cosmetics are not subject to FDA premarket approval
- ✓• “FDA Registered” logo not allowed

EU

- Fill electronic application and designate responsible personnel for each product

ASEAN

- According to country

Use of ingredients

USA

- ✓ Can use almost any raw materials without any approval or limitation
- ✓ Restriction for color additives,
- ✓ Short list of prohibited and restricted ingredients

EU

- More exhaustive lists
- Ingredients are regulated by the **annexes**:
- Annex II: banned ingredients; ممنوع
- Annex III: restricted ingredients; مسموح بشروط
- Annex IV: positive list of colors; اللائحة المسموحة
- Annex VI: positive list of preservatives; المواد الحافظة المسموحة
- Annex VII: positive list of UV filters;

ASEAN

- Same As EU
- With more restriction in China
- China positive list is a major blockage to innovation and consumers travel to other countries, to buy the latest product they want!

EU:

أكسيد الزنك كريم

مواد حافظة

Ingredients:

Aqua, Stearic Acid, Cetyl Alcohol, Stearyl Alcohol, Paraffinum Liquidum, Glycerine, Bisabolol, Allantoin, Titanium Dioxide, Niacinamide, Retinyl Palmitate, Ascorbic Acid, Methylchloroisothiazolinone, Methylisothiazolinone, EDTA, Lactic Acid.

38	4-Isopropyl-m-cresol	O-CYMEN-5-OL	3228-02-2	221-/61-/		0.1%
39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	METHYLCHLOROISOTHIAZOLINONE AND METHYLISOTHIAZOLINONE	26172-55-4, 2682-20-4, 55965-84-9	247-500-7, 220-239-6	Rinse-off	0.0015% (of a mixture in the ratio 3:1 of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one
40	Methylisothiazol-3(2H)-one	CHLORISOTHIAZOLINONE	55-58-4, 55-05-4	200-239-7, 200-239-8		0.0015%

حسب تعليمات
الدقائد الأوروبية
حدود المواد الحافظة
بتركيز 0.0015%
mixture يستعمل
Rinse-off

لأنه؟
Contact allergy

Is methylisothiazolinone a preservative causing high rates of allergy?

MCI/MI is one of the most frequent causes of preservative contact allergy and early studies showed that both MI and MCI are sensitizers. The prevalence of MI contact allergy is already around 1.5% and sources of exposure are associated with occupation, cosmetic products or household products.



nih.gov

<https://pubmed.ncbi.nlm.nih.gov> > ...

Methylisothiazolinone contact allergy: a review - PubMed

Huda Beauty pays nearly \$2m to settle Neon Obsessions lawsuit

تفاهيت
استخدمت الوان غير
مسموح استخدامها حول العين.

By Sarah Parsons 25-Jul-2022



Regulatory | *Finance*

The Dubai-based make-up brand used banned ingredients in the palette line





Huda Beauty was founded by Dubai-based influencer and make-up artist Huda Kattan

Huda Beauty will pay nearly US\$2m to settle a two-year lawsuit by consumers that the Dubai-based make-up brand used illegal ingredients in its Neon Obsessions palettes.

The brand, founded by influencer Huda Kattan, was accused of using pigments banned for use around the eye area by the Food and Drug Administration (FDA).

The US lawsuit claimed that Huda Beauty concealed the prohibited ingredients to consumers by hiding warning labels, including 'not intended for the eye area', behind outer packaging.

Despite not being suitable for the eye area, Neon Obsessions was packaged in the same format as the brand's other eyeshadow palettes and used campaign imagery of Kattan wearing the product as eyeshadow.

The ingredients in question were Red 6 (Ci 15850), Yellow 10 (Ci 47005), Red 22 (Ci 45380) and Red 28 (Ci 45410) due to potential eye irritating and staining properties.

The lawsuit, initially settled in October 2021, will see Huda Beauty pay \$1.93m to resolve the claims and \$1.2m in legal fees for the plaintiffs.

ألوان ال Neon غير مسموح استخدامها حول العين حسب FDA US



Testing the product safety

USA

- Cosmetics have to be safe and manufacturer are responsible
- No guidelines on how to assure safety
- In-market surveillance

EU

- Provide information on assessment of product safety *No specific standards*
- Prohibit animal testing
- Nano material containing cosmetics shall be authorized before market

ex: Zinc oxide nano

ASEAN

- Previously mentioned

*Wishing you all the best ♡
Anfal Al-naimat*

why?

- * more penetration.
- * more toxicity.