

Legal and Regulatory Tips Cosmetics Business in Brazil

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Cosmetics?

Preparation comprised by natural and/or synthetic substances for using in connection with the external side of the human body, skin, scalp, nails, lips, external aspects of intimate organs and mouth with the main or exclusive aim of cleaning, perfuming, altering appearance, amending odor, protecting and/or keeping them in good format

Natural? Concept of natural is still a BIG challenge

Synthetic? Comprehensive list of banned, protected subs: Individual look

External? Cosmeceuticals, nutricosmetics? Pills, API-containing sun proof

Human? Vets products are not covered by this presentation

Scalp? Shampoos with internal aspects

It is all about marketing and advertising: Mind the claims!

If your product claims to treat, it might become a medicine or device

Cosmetics Business 101

Brazilian company responsible for the extraction, production, manufacturing, importing, exporting, tooling, storaging, transformation, sinthetizing, packaging, dispatching, transporting, distribution

Cosmetic company must complete a three-tier level of certification: F, S, M

Foreign company must have a local representation: proxy or subsidiary

BR agent holds ALL liability, responsibility for the product: Profit margin...

Local representative must own the product registration

Foreign company + local representative = Very good agreement...

Trademark, domain name = try and keep them all accountable!

6-months = Reasonable timeframe. Less than this? Wisdom or adventure

Facts...

ANVISA is the Brazilian FDA: Large umbrella of activities

Regulation of all aspects of supply chain and life cycle of cosmetics

Definitions, new ingredients, banned products, registration/notification

Cosmetic products: Must be registered or notified before market entry

Cosmetic companies: Must be certified, accredited by ANVISA – CDC liability

Failure to comply with regulations (following administrative proceeding):

(a) Companies: fines up to USD1mi and corporate banning

(b) Products: market withdrawal, corporate fines

Legal, regulatory check list

Foreigners must not market cosmetics

Cosmetic companies must obtain permits, as well as products

Proxy mechanisms? Yes, but watch it carefully!

Document assembly: FDA, Europe, Japan? Validity of foreign documents

Pricing, revenue analysis

Due diligence of the local agent: RADAR + AFE (F) + Visa (S) + Alvará (C)

Supply chain analysis: distribution + exclusivity + import duties

Standardization, terminology, size, weight, dimension: ABNT and INMETRO

Brazilian market does not discriminate. It is hard for everybody!

סבלנות והתמדה!



About ZCBS

ZCBS: Brazil's pioneer, most active law firm dealing with Israeli biz
Providing one stop shop legal, regulatory guidance to IL's companies
One of Brazil's strongest Life Science, FDA-regulated practice
This presentation and more info? israel@zcbs.com.br

Obrigado!

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