

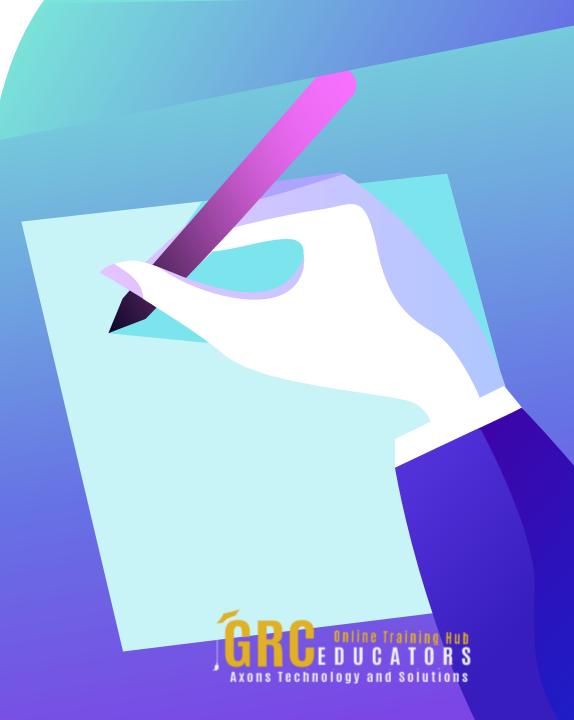
Webinar on

Gray Areas in Cosmetic Regulation. Marketing Claims That Avoid Regulatory Issues

Date: August 10, 2021

Areas Covered

- FDA/FTC/BBB what are their roles?
- Regulatory compliance
- Making claims
- Claim substantiation
- Competative advantage
- Porbiotics, prebiotics
- Natural, glutin free GMO free
- Vegan
- Label vs labeling
- Organic
- CBD, Hemp, THC
- Preservative-free
- Vegan
- Certification



This webinar will outline issues that should be considered when changing marketing strategies as a result of an unclear regulatory atmosphere.

PRESENTED BY:

John Misock - is serving in his fourth career as Senior Consultant with Ceutical Labs, Inc. Flower Mound, TX. John retired from the FDA's Office of Cosmetics and Colors in June 2019 where he served as an SME in the areas of personal care product microbiology and manufacturing Prior to FDA John served in a global capacity with Estee Lauder Companies responsible for regulatory compliance in all manufacturing facilities.

Date: August 10, 2021

Time: 02: 00 PM EST

Duration: 60 Minutes

Price: \$179

Webinar Description

FDA has a history of avoiding discussion of popular issues and leaving the course of history to the imagination of industry to push the boundaries of regulatory compliance. The unwillingness by FDA to address issues like "natural", "probiotic", "CBD" and other popular issues, creates an opportunity to add market potential, but it also creates hazards to avoid for FDA-regulated products. Dietary supplements, as a group, is usually early to jump on board creating new marketing avenues that eventually move into the cosmetic/personal care space. Since dietary supplements and cosmetics do not require pre-market approval, barriers to the entrance to the market are much lower than OTC drugs. Issues that arise regarding the safety of ingredients also tend to drag behind what consumers are able to tolerate.

CBD in FDA-regulated products is a classic example of the FDA,s reticence to get in front of issues. This is much different than other countries that tend to come out early with restrictive legislation. FDA-regulated industries are smart to take advantage of the FDA's lax stance on regulatory compliance of popular issues. If you have an idea go for it! To avoid regulatory backlash, make sure you are not breaking existing laws and regulations. Current regulations are not clear thus there is a considerable amount of speculation as to what is acceptable and what isn't.



For cosmetics, the biggest problem is avoiding making drug claims and clearly stating a cosmetic function for the special ingredients that support claims. Cosmetics are unique because there is no requirement to substantiate cosmetic claims. Dietary supplements are required to substantiate any claims promoting the product which makes it much more difficult to avoid regulatory problems. Even if FDA decides not to enforce specific issues like natural, probiotic, or other labeling issues, The Federal Trade Commission can take action against marketers if their claims are deemed to be misleading or inflated. Finally, if you claim to be better than your competitors, The Better Business Bureau's Advertising Board can step in to level the playing field. This usually comes about when one competitor calls another to the carpet for unsubstantiated claims that their product is superior. If BBB mediation does not work, there is always court!

Organic is a different beast. The problem arises when cosmetics claim to be organic. FDA has scrutinized Organic Cosmetics because truly organic products do not contain preservatives and therefore tend to have micro problems. The same can be said for preservative-free claims.



Vegan, is no issue for labeling as long as it is in fact true. Companies that operate as vegan or vegan friendly often call each other out for stretching the truth. Being certified as vegan has no regulatory significance, but can be challenged by competitors and the blogosphere.

An important thing to remember is the distinction between "labels" and "labeling". FDA considers both when determining regulatory compliance. If you are making claims, everything that is available on your website is labeling, including testimonials.

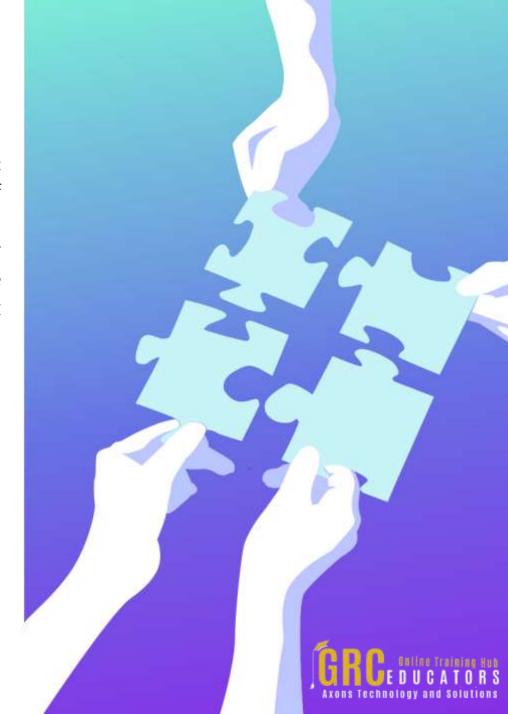
Making changes to your products to avoid negative connotations regarding ingredients, such as talc, parabens and other ingredients currently in the public's eye can be problematic. Knowing the facts is a must. Changing formulations to avoid negative attention should not be made hastily. Removing parabens in order to be able to say "preservative free" can result in big problems, including recalls.

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Topic Background

FDA does not place a high priority on clarifying regulatory issues that arise as a result of marketing trends and health issues that are in the public psyche. As a result these gray areas in regulation breed a mountain of misinformation that morphs into headaches for consumers and manufacturers. FDA leaves the interpretation of vague guidance on many issues up to industry to figure out. If the industry cannot get it right the Federal Trade Commission (FTC) can step in to bring order to the market place. Also, the Better Business Bureau can get involved if FDA and FTC fail to take action.



Who Should Attend?

Marketing Directors, Brand Owners, and New startups.



Why Should You Attend?

If you intend to create a competitive advantage by making product claims that are not directly addressed by FDA or if you market products that contain ingredients that are in regulatory limbo you should attend this webinar. Although these issues are not clearly regulated by FDA, they can still be problematic when you choose to go down the path. You can avoid regulatory problems if you know where the lines are and stay away from the edge. If you are willing to step into these markets make sure you know all of the risks. Is it worth jumping into the next big craze? What happens when FDA/FTC decide to take action? How did we get from yogurt to probiotics? Can you use cannabinoids in cosmetics? What is natural, glutin free GMO free, etc?





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