You Wear It Well (or Do You?): FDA Objects To These Skincare Companies' Unapproved New Drug Claims

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In the 1972 hit, "You Wear it Well," Rod Stewart sang about a woman and offered the classic line, "Madame Onassis got nothing on you." The tune came to mind when reading four Warning Letters issued by the Food and Drug Administration in July against skincare companies marketing unapproved new drug claims. FDA didn't think the companies wore it well.

We have written in the past about the Food and Drug Administration's enforcement against skincare companies marketing claims that the agency considered to be unapproved new drugs.[1] FDA is out in force again with a slew of Warning Letters.[2] All of the Letters came from District offices.

Without describing each enforcement letter in detail, we will note some, but not all, of the claims to which FDA objected:

- Cellular regeneration
- Inflammation
- Preventing wrinkles, age spots and redness
- Collagen production
- Promotes cell growth
- Anti-anxiety properties and anti-bacterial properties
- Encourages healthy cell regeneration
- Offers alternatives to Botox, Restylane and other sometimes harmful, costly and invasive procedures
- An excellent alternative to medically administered treatments
- Vitamin A: useful for regenerating skin and encouraging cellular renewal… used in the treatment of psoriasis
- Vitamin C: collagen boosting Vitamin C, also works to strengthen capillary walls for firm skin tone ... Shown to help control hyperpigmentation and to enhance the skin's immune system
- Safe and non-toxic, topical alternative to injections
- Reverse skin damage through the stimulation of new skin from the stem cell reservoirs
- By allowing the stem cells to increase their potency and promote cell regeneration, tissue is reconstructed to a denser quality and more elastic skin
- Activates epidermal regeneration and targets damage done by free radical agents

FDA asserted that such claims made the products "drugs," because they were intended "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "intended to affect the structure or any function of the body" (referring to the statutory definition of "drug").

1 See http://www.agg.com/The-First-Cut-is-the-Deepest--FDA-Issues-a-Warning-Letter-to-a-Skincare-Company-for-Marketing-Unapproved-New-Drugs-06-16-2016/

2 See e.g., www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm513404.htm; www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm514901.htm; www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm514904.htm; www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm515078.htm

AGG Observations

Skincare companies must continue to review label and promotional claims to ensure regulatory compliance. FDA does not require prior approval to market cosmetics; it does for new drugs. We have seen an increase in FDA enforcement of skincare claims that make drug-like claims. Companies should pay specific attention to claims that reference a particular disease or medical condition, such as psoriasis or inflammation, or that suggest the product is an alternative to a drug. Those statements are more likely to draw scrutiny from FDA, another regulatory body, or a competitor.

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