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ALERTS

Food, Drug & Device Law Alert - FDA Extends Comment Period On Draft Guidance That Could Require An IND For Cosmetics, Dietary Supplements And Food Research

February 11, 2014 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

In September 2013, the FDA issued a draft Guidance titled, "Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND." Given that INDs are typically associated with pharmaceuticals, members of other industries subject to FDA regulation may not have paid close attention to this draft Guidance. As it turns out, however, the draft Guidance could have significant implications for cosmetics, dietary supplements, and research.

As to cosmetics, the draft Guidance provides that studies of ingredients or products marketed as cosmetics require an IND if the ingredient is being studied for use to affect the structure or function of the body or to prevent, treat, mitigate, cure, or diagnose a disease According to the draft Guidance, "[t]his is true even if the study is intended to support a cosmetic claim about the ingredient or product's ability to cleanse, beautify, promote attractiveness, or alter the appearance, rather than a structure/function claim."

With respect to dietary supplements and food, the draft Guidance also states that an IND may be required in certain circumstances. For dietary supplements, "if the clinical investigation is intended to evaluate the dietary supplement's ability to diagnose, cure, mitigate, treat, or prevent a disease, an IND is required," per the draft Guidance. In the case of food, "if the intent of [a] study [i]s to evaluate the beneficial effects (beyond nutritional effects) of binding [a] newly found receptor, the study would require an IND." As another example, the draft Guidance offers that "if the intent of [a] study [i]s to demonstrate an effect of the food in decreasing HbA1c levels in diabetic patients or an effect of the food to desensitize or raise threshold levels of allergic reactivity in sensitive individuals, the study would require an IND."

The draft Guidance appears to run contrary to the Food, Drug & Cosmetic Act and existing regulations that establish a scheme requiring different levels of evidence to support claims depending on whether the claims support classification of the product for which claims are made as a drug, cosmetic, dietary supplement, or food. Also, FDA pre-approval may or may not be required depending on the type of claim being made.

The draft Guidance has the potential to impose substantial expense and delay on the cosmetics, dietary supplement, and food industries if they must pursue an IND (and perhaps well-controlled clinical trials) and obtain FDA pre-marketing approval to sell their new products. Thus, participants in those industries may wish to review the draft Guidance, consider its

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implications for their business, and submit timely comments expressing any concerns. The new deadline to submit comments is April 7, 2014.

For more information, contact the Barnes & Thornburg attorney with whom you work or one of the following attorneys:

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