OBTAINING APPROVAL OF FOOD AND COSMETIC PRODUCTS EMPLOYING NANOTECHNOLOGY - NO SMALL TASK

On April 25, 2012, the United States Food and Drug Administration ("FDA") issued two new draft guidance documents on the use of nanotechnology in food and cosmetics. Specifically, the FDA published (1) *Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives*; and (2) *Draft Guidance for Industry: Safety of Nanomaterials in Cosmetic Products*. As with all guidance documents, these recent publications do not create legally enforceable responsibilities. Rather, they are designed to provide manufacturers with assistance in determining how to ensure that food and cosmetic products containing engineered nanomaterials meet the applicable safety and regulatory requirements. They also provide manufacturers with some valuable insight into the FDA's current thoughts about the use of nanotechnology and future regulation.

POTENTIAL CHANGES TO PRODUCT PERFORMANCE

As noted by the FDA in the guidance documents, "nanotechnology" involves the manipulation of materials measured in nanometers (equal to one-billionth of a meter). When certain materials are manipulated at the nano level, their chemical, physical, and biological properties can be altered, causing those materials to behave differently from their counterparts composed of larger particles. Among other things, changes at the nano level can result in increased structural integrity, increased solubility, changes in color, and altered chemical activity.

Although these changes can increase the performance of products to the benefit of manufacturers and consumers alike, they also have the potential to affect the safety of products. As an example, the FDA suggests that changes to the properties of food and cosmetic products, including their ingredients, can possibly change the level at which a food or cosmetic product can become toxic. Similarly, these changes may affect the extent to which materials can be absorbed by and move within the body. In addition to the potential safety concerns, the use of nanomaterials might change the regulatory status of an existing product or the way in which an existing product is used. These changes could require manufacturers to obtain new or additional regulatory approval.

ISSUES TO CONSIDER

In light of these potential changes, the FDA's recent guidance documents are intended to highlight issues that manufacturers of food and cosmetics should consider when employing nanomaterials in their products. Most notably, the FDA acknowledges that "nanotechnology" is a

broad science that covers a wide range of materials and products. Thus, the FDA states that it does not "categorically judge all products containing nanomaterials or otherwise involving application of nanotechnology as intrinsically benign or harmful." Rather, it concludes that as with any other product, compliance and safety issues should be addressed on a case-by-case basis taking into consideration the intended use of the product.

The general theme of the FDA's guidance documents is that manufacturers may not be able to rely on existing procedures and testing methods to obtain approval of products containing nanomaterials. To help manufacturers determine which issues to consider when designing and obtaining approval of a food or cosmetic product employing nanomaterials, the FDA makes the following recommendations:

- Safety assessments of food and cosmetic products containing engineered nanomaterials should be based on data relevant to the nanometer version of the substance, not the version consisting of larger particles. Thus, additional or different testing methods may be necessary to determine the safety of food and cosmetic products containing engineered nanomaterials.

- The use of nanotechnology in the manufacturing process for a food product may constitute a "significant change," such that a new authorization is required for that product.

- A food product with new functional properties due to the use of engineered nanomaterials likely would not be covered by an existing "Generally Recognized as Safe" determination for a related food manufactured without nanomaterials.

- Manufacturers of cosmetics should consider modifying traditional toxicity testing with respect to factors such as dosing formulations, methods to prevent agglomeration of particles, stability and purity conditions, and other variables.

- Due to the potential for engineered nanomaterials to translocate within the body, the dose of nanomaterials in organs other than the target organ should be considered when developing or modifying toxicological testing methods and evaluating test data.

NO ONE-SIZE-FITS-ALL SOLUTION

Given these and the other considerations highlighted in the FDA's guidance documents, the decision to employ nanotechnology to create a new, or improve an existing, food or cosmetic product is not one that can be made lightly. It requires a thoughtful analysis of all aspects of the product lifecycle, especially the regulatory approval process. Although the FDA's recommendations can be characterized as vague, its recommendations are consistent with its position that these types of decisions must be made on a case-by-case basis. There is no "one-size-fits-all" solution. Accordingly, the FDA recommends that manufacturers contact it for assistance. Doing so during the early stages, as well as contacting outside consultants, could help avoid costs and delays later in the process.

ADDITIONAL INFORMATION

For further information or questions about the FDA's guidance documents, please contact any member of Tucker Ellis LLP's Nanotechnology Task Force.

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