Edible Nanotechnology

By

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On April 20, 2012, the U.S. Food and Drug Administration (FDA) issued two new draft guidance documents on the use of nanotechnology in food and cosmetic products -- "Guidance for Industry: Assessing the Effects of Significant Manufacturing Process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," which is available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm300661.htm, and "Guidance for Industry: Safety of Nanomaterials in Cosmetic Products," which is available at http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm300886.htm. While these documents are not binding and are subject to change, they do represent the direction and background of FDA's thinking on this evolving topic. This article summarizes each.

Overview

The guidance documents reaffirm FDA's view that it regulates products not technologies, that the science of nanotechnology is expanding, and that its oversight of nanotechnology is iterative and adaptive. The guidance documents themselves will be useful to entities subject to FDA jurisdiction, and provide much needed clarity on certain topics, including

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what is a "significant change" in a manufacturing process such that manufacturers should be mindful of the potential regulatory implications of such changes.

Guidance on Food Contact

The primary point in FDA's draft guidance on the use of nanotechnology in food is to determine when use of nanotechnology in manufacturing food ingredients and food contact substances (FCS), including packaging and pigments, may affect the safety of the end product. FDA takes care to outline the regulatory pathways for various components of food and the steps necessary to demonstrate their safety. FDA points out that alteration in particle size distribution on the nanometer scale, which can alter the physical and/or chemical properties of food ingredients and FCSs, can sometimes be "significant" manufacturing changes requiring new testing or regulatory filings.

The implications of this new draft guidance on manufacturers seeking to utilize nanotechnology could be significant. FDA is signaling that a new regulatory filing will be required in most circumstances when manufacturing changes result in nanoscale dimensions of food ingredients, FCSs, and color pigments -- especially if the substance is already in the market. Consultation with FDA is encouraged, particularly for GRAS substances as manufacturing changes involving nanotechnology are likely to involve a new regulatory filing.

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Guidance on Cosmetics

With the exception of color additives, FDA does not subject cosmetic products or cosmetic ingredients to premarket approval. Manufacturers may use any ingredient, except for color additives, as long as such use does not cause the product to become adulterated or misbranded. Manufacturers or distributors should obtain all the data and information necessary to substantiate the safety of the product before marketing.

As with food substances and ingredients, cosmetic ingredients at the nanoscale might change the product's performance, quality, safety, and/or effectiveness. In addition, use of nanomaterials may alter the bioavailability of the cosmetic formulation. In some cases, the traditional tests relied upon to determine safety might not be fully applicable.

FDA is encouraging manufacturers to meet with it before incorporating new nanomaterials or an altered nanosized version of an existing ingredient into a product's formulation to discuss the test methods and data needed to substantiate the product's safety. This might include chronic toxicity and other long-term toxicity data.

For purposes of analyzing uptake and absorption, FDA divides nanomaterials into two groups: (1) soluble and/or biodegradable nanoparticles that disintegrate into their molecular components upon application to skin; and (2) insoluble and/or biopersistent nanoparticles. FDA notes that risk assessment based on mass metrics may be adequate for the soluble nanoparticles, but insoluble components may require other metrics.

FDA notes that there is a substantially increased probability for entry of nanomaterials through skin with an impaired barrier layer (*e.g.*, sunburned, atopic, eczematous, psotiatic skin). Use of nanomaterials in aerosolized products may also result in exposure of nanomaterials via the respiratory tract. Additional or altered studies may also be needed for this category of products.

Comments on the guidance documents are due by July 24, 2012. The documents are important, and stakeholders are urged to review them and comment as needed.

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