THE
NATIONAL LAW REVIEW

FDA Proposed Rule for OTC Sunscreen Drug Products Addresses Sunscreens Containing Nanomaterials

Friday, February 22, 2019

The Food and Drug Administration (FDA) is scheduled to publish a proposed rule in the *Federal Register* on **February 26, 2019**, that would put into effect a final monograph for nonprescription, over-the-counter (OTC) sunscreen drug products. The proposed rule describes the conditions under which FDA proposes that OTC sunscreen monograph products are generally recognized as safe and effective (GRASE) and not misbranded. FDA notes that it has not established regulatory definitions of nanotechnology, nanomaterial, nanoscale, or other related terms. As described in FDA's guidance for industry "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology," at this time, when considering whether an FDA-regulated product involves the application of nanotechnology, FDA asks:

1. Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately one nanometer (nm) to 100 nm).

In addition, because materials or end products can also exhibit related properties or phenomena attributable to a dimension(s) outside the nanoscale range of approximately one nm to 100 nm that are relevant to evaluations of safety, effectiveness, performance, quality, public health impact, or regulatory status of products, the proposed rule states that FDA will also ask:

2. Whether a material or end-product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (µm) (1,000 nm).

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According to the notice, FDA "will apply these considerations broadly to all FDA-regulated products, including sunscreen products." For the purpose of the proposed rule, FDA uses the term "nanomaterial" generally to refer to materials falling within either point 1 or 2 above.

FDA notes that nanomaterial forms of the active ingredients zinc oxide and titanium dioxide have been used in marketed OTC sunscreens. In addition to nanomaterial forms of zinc oxide and titanium dioxide, other nanomaterials are also reported to have been used, or promoted or studied for possible use, in sunscreen products. FDA states that, "having examined the scientific information in the record, including for nanomaterial forms of zinc oxide and titanium dioxide, FDA is not now proposing conditions of use for these two active ingredients under the sunscreen monograph that distinguish nanomaterials from other forms of these ingredients." FDA "also does not propose to categorically classify sunscreen products that are manufactured using nanotechnology or contain nanomaterials as GRASE or not, solely on that basis." Manufacturers of products

containing nanomaterials marketed under the OTC sunscreen monograph remain responsible for ensuring that the product satisfies all applicable legal requirements. FDA "encourages manufacturers of such products to consult with FDA to facilitate a mutual understanding of specific scientific or regulatory issues relevant to their product."

FDA invites comment on the following topics:

- Specific nanomaterials or types of nanomaterials that have been used or proposed for use in OTC sunscreen products;
- Concerns about sunscreen product safety, effectiveness, or quality associated with the use of nanomaterials in OTC sunscreen products, with supporting data;
- Need for, and proposals of, specifications or limitations for particular nanomaterials for use in OTC sunscreen products;
- Any particular nanomaterials that you believe should not be permitted for use in OTC sunscreen products, along with supporting scientific information; and
- FDA's proposed regulatory approach and/or alternative regulatory approaches to the use of nanomaterials in OTC sunscreen products.

In 2011, FDA published an advance notice of proposed rulemaking (ANPR) that identified sunscreen dosage forms considered either eligible or ineligible for inclusion in the sunscreen monograph, and specifically requested comments on the safety and efficacy of spray sunscreens. FDA notes in the forthcoming proposed rule that several comments on the ANPR "expressed concern about the potential inhalation risk from exposure to spray sunscreens that contain nanomaterials (as both active and inactive ingredients)." One comment also recommended that FDA require the presence of such ingredients to be disclosed on spray sunscreen labels. FDA states that it "is not now proposing conditions of use, including labeling, for spray sunscreens that distinguish based on the presence of nanomaterials because we are proposing that any sunscreen spray that contains any particles smaller than 5 µm when it is dispensed from the consumer container would not be GRASE." With respect to nanomaterials in spray sunscreens, FDA notes that "the primary determinant of inhalation risk is the size of the particles in emitted sprays, which may be larger than individual formulation components. Nanoscale ingredients would not pass the particle size limitations for spray sunscreens; therefore, if they were to be detected when sprayed from the consumer container during particle size testing, the sunscreen could not be marketed under the OTC monograph." Publication of the proposed rule in the *Federal Register* will begin a 90-day comment period.

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