FDA Will Publish Proposed Rule for OTC Sunscreen Drug Products

Monday, February 25, 2019

The U.S. 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. According to FDA's February 21, 2019, press release, the rulemaking intends to bring nonprescription, OTC sunscreens that are marketed without FDA-approved applications up to date with the latest science to ensure better that consumers have access to safe and effective preventative sun care options. Among its provisions, the proposal addresses sunscreen active ingredient safety, dosage forms, and sun protection factor (SPF) and broad spectrum requirements. It also proposes updates to how products are labeled to make it easier for consumers to identify key product information. FDA states that it is issuing the proposed rule to put into effect final monograph regulations for OTC sunscreen drug products as required by the 2014 Sunscreen Innovation Act (SIA). Publication of the
proposed rule in the Federal Register will begin a 90-day comment period.

Summary of Key Provisions of the Proposed Rule

Proposed GRASE Status of Active Ingredients Listed in the Stayed 1999 Final Monograph

FDA proposes that, of the 16 currently marketed active ingredients, two ingredients -- zinc oxide and titanium dioxide -- are GRASE for use in sunscreens, and two ingredients -- aminobenzoic acid (PABA) and trolamine salicylate -- are not GRASE for use in sunscreens due to safety issues. According to FDA, there are insufficient safety data to make a positive GRASE determination at this time for the following 12 ingredients: cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, and avobenzone. To address these 12 ingredients, FDA asks industry and other interested parties for additional data. FDA states that it is working closely with industry and has published several guidances to make sure companies understand what data it believes are necessary to evaluate safety and effectiveness for sunscreen active ingredients, including the 12 ingredients for which FDA is seeking more data.

FDA requests specific comment regarding certain active ingredients:

- Titanium dioxide: FDA invites comment (including supporting data) on whether sunscreens containing titanium dioxide are negatively impacted by the potential photocatalytic effects of that ingredient and, if so, to what extent; and on additional regulatory conditions, if any, that are necessary to address this potential issue; and

- Oxybenzone: The available literature also raises questions about the safety of use of oxybenzone-containing sunscreens in young children because of the potential for higher absorption and bioaccumulation of oxybenzone in this population. FDA invites input and comment on appropriate studies and/or age restrictions to address these pediatric issues, as well as input on the extent to which reactive oxygen species generation is a concern and whether labeling language is necessary to address the risk of allergic reactions associated with oxybenzone use.

Proposed Requirements Related to Dosage Forms

FDA proposes that dosage forms that are GRASE for use as sunscreens include sprays, oils, lotions, creams, gels, butters, pastes, ointments, and sticks. FDA proposes that powders be eligible for inclusion in the monograph, but requests additional data before powders can be included in the monograph. FDA proposes that wipes, towelettes, body washes, shampoos, and other dosage forms be categorized as new drugs because FDA has not received data showing they are eligible for inclusion in the monograph.

FDA states that it thinks that consumers should be warned to stay away from sources of flame while a flammable or combustible sunscreen spray dries. For this reason, it
proposes to require that each batch of a sunscreen spray product that meets the definition of flammable or combustible be tested for drying time in accordance with written specifications. If the drying time is less than five minutes, FDA proposes to require that the labeling state: “Wait 5 minutes after application before approaching a source of heat or flame, or before smoking.” No additional information is provided as to what constitutes a “source of heat.” If the drying time is at least five minutes but less than ten minutes, FDA proposes that the labeling state: “Wait 10 minutes after application before approaching a source of heat or flame, or before smoking.” FDA proposes that a sunscreen spray that is flammable or combustible and that takes ten minutes or more to dry would not be GRASE because of the possibility of consumers approaching sources of fire during such an extended drying period. FDA invites comment on this approach.

FDA invites comments and data on the following topics related to powder sunscreens:

- What amounts of powder sunscreens do consumers typically dispense;
- What amounts of powder sunscreens are effectively transferred to the skin;
- How uniform is the sunscreen application across the sun-exposed area of the skin;
- How frequently do consumers reapply the product;
- Does rubbing a powder into the skin change sunscreen effectiveness;
- Are powder dosage forms water-resistant, and if not, is a direction to reapply every two hours sufficient to assure their safe and effective use;
- Can the powder dosage form be used safely and effectively over all areas of skin exposed to the sun, or should this dosage form be limited to the face;
- What factors, if any, should FDA consider in connection with particle size limitations or test methods for sunscreen powders; and
- Are there important differences among powder types (e.g., loose, compact) or applicators that would affect particle size testing?

**Proposed Maximum Sun Protection Factor and Broad Spectrum Requirements**

FDA proposes to raise the maximum proposed SPF value on sunscreen labels from SPF 50+ to SPF 60+. FDA notes that while the proposed cap for SPF labeling is SPF 60+, it proposes to permit the marketing of sunscreen products formulated with SPF values up to 80. According to the proposed rule, this formulation margin is intended to provide manufacturers with formulation flexibility that FDA hopes will: (1) help facilitate the development of products with greater Ultraviolet A (UVA) protection; and (2) more fully account for the range of variability in SPF test results for sunscreen products labeled SPF 60+. FDA proposes not to allow the marketing (without an approved new drug application (NDA)) of sunscreen products with SPF values above SPF 80.
FDA notes that the body of scientific evidence linking UVA exposure to skin cancers and other harms has grown significantly since its 2011 final rule regarding labeling and effectiveness testing for sunscreen products for OTC human use. According to FDA, the evidence raises concerns about the potential for inadequate UVA protection in marketed sunscreen products, particularly in high SPF sunscreen products that either do not pass the current broad spectrum test or (though they pass the current broad spectrum test) have inadequate uniformity in their UVA protection. FDA proposes to require sunscreens with an SPF value of 15 or higher to also provide broad spectrum protection. For broad spectrum products, FDA proposes that as SPF increases, the magnitude of protection against UVA radiation also increases. FDA states in its press release that these proposals “are designed to ensure that these products provide consumers with the protections that they expect.”

**Proposed Principal Display Panel (PDP) Labeling Requirements**

FDA proposes new sunscreen product label requirements that are intended to assist consumers in more easily identifying key information, including the addition of the active ingredients on the front of the package to bring sunscreen in line with other OTC drugs; a notification on the front label for consumers to read the skin cancer/skin aging alert for sunscreens that have not been shown to help prevent skin cancer; and revised formats for SPF, broad spectrum, and water resistance statements.

**Proposed Requirements Related to Final Formulation Testing Processes and Recordkeeping**

To ensure that FDA can assess compliance with its regulations, it proposes to require records of required final formulation testing of sunscreen products to be maintained for one year after the product expiration date or, if the product is exempt from expiration dating (as most sunscreens are), for three years after distribution of the last lot labeled in reliance on that testing. FDA proposes to require responsible persons to keep records of sunscreen formulation testing, and clarifies that required records would be subject to FDA inspection.

**Proposed Status of Sunscreen-Insect Repellent Combination Products**

The proposed rule also addresses sunscreen-insect repellent products, which are jointly regulated by FDA as sunscreen drugs and by the U.S. Environmental Protection Agency (EPA) as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In 2007, FDA and EPA both issued advance notices of proposed rulemaking (ANPR) requesting comment on the appropriate regulatory status of these products. FDA proposes to classify these products as Category II (proposed to be not GRASE or to be misbranded) “because incompatibilities between FDA and EPA labeling requirements prevent these products from being labeled in a manner that sufficiently ensures safe and effective use of the sunscreen component and provides adequate directions for use.” In addition, according to the proposed rule, “there are data suggesting that combining some sunscreen active ingredients with the insecticide DEET may increase absorption of either or both components.” FDA solicits comments and data about how to reconcile the labeling of sunscreens.
and insect repellents, such that a combined product could meet Federal Food, Drug, and Cosmetic Act (FFDCA) requirements for OTC sunscreen drugs.

**Proposed Actions to Effectuate Lifting of Stay and Harmonize Impacted Regulations**

In 1999, FDA published a final sunscreen monograph that included 16 sunscreen active ingredients along with the conditions (including maximum concentrations) under which these ingredients would be considered GRASE for use in sunscreens. The effective date for complying with the 1999 final monograph was May 21, 2001. This deadline was first extended and then stayed until further notice to provide additional time to resolve various outstanding issues, such as the labeling and testing of finished OTC sunscreen products. As a result, the stayed 1999 final monograph has never been in effect.

FDA proposes to lift the stay on the 1999 final monograph, subject to certain revisions. FDA proposes revisions to the regulations necessary to effectuate the lifting of the stay and to harmonize any impacted regulations.

**Sunscreens Containing Nanomaterials**

As reported in our February 21, 2019, blog item, 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;
- The 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.
Commentary

This is an important notice and stakeholders are urged to read it and assist FDA by responding to the questions asked. How FDA went about determining what is and is not GRASE is a significant template for other such assessments and, as such, merits close review. The final monograph would not address the six pending sunscreen active ingredients that were originally submitted under the procedures established in the time and extent application regulation and that are now being addressed through the SIA process. FDA notes that the safety data described as necessary to evaluate the safety and effectiveness of sunscreen products containing the six active ingredients are the same as that needed to establish that the active ingredients listed in the stayed 1999 final monograph are GRASE for use in sunscreen products. According to FDA, since publication of the stayed monograph, changed conditions such as substantially increased sunscreen usage and exposure and evolving information about the potential risks associated with these products mean that additional safety data are now necessary. SIA calls for FDA to issue a final OTC sunscreen monograph to be effective within five years of enactment, or by November 26, 2019.

Nano stakeholders will be pleased with FDA’s agnostic approach to the nano-based technologies considered in the notice. Stakeholders remain concerned with regulatory classifications or disclosure requirements that are based purely on the inclusion of nanomaterials. FDA requests comment on its proposed regulatory approach and/or alternative regulatory approaches to the use of nanomaterials in OTC sunscreen products, providing stakeholders an opportunity to express their support of FDA’s approach.

We note that environmental groups have targeted the ingredients oxybenzone and octinoxate, claiming that they play a role in the degradation of coral reefs. While the science may not yet be conclusive, as reported in our May 4, 2018, blog item, on May 1, 2018, Hawaii passed a bill banning the sale or distribution of any sunscreen that contains these ingredients, and Governor David Ige (D) signed the bill in July 2018. A similar bill was introduced in the California legislature in December 2018, and on February 5, 2019, the Key West, Florida City Commission voted to ban sunscreens containing oxybenzone or octinoxate. Both the Hawaii and Key West bans will begin in January 2021. Under FDA’s proposed rule, oxybenzone and octinoxate would be classified as Category III (additional data needed).

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