Sunscreen Innovation Act Changes FDA Review Process For More Than Just OTC Sunscreens

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On November 26, 2014, the President signed into law the "Sunscreen Innovation Act." The Act is primarily intended expedite the Food and Drug Administration's (FDA) procedures for approving new sunscreen active ingredients and ingredient blends for use in nonprescription sunscreen products under the Federal Food Drug and Cosmetics Act (FDCA), and address the current backlog of sunscreen ingredient applications pending at FDA.[1] The Act will help provide for new innovative sunscreen products in the marketplace that would further protect consumers from harmful exposure to ultraviolet light.

Importantly, however, the Act also sets forth a new framework for FDA to expedite similar approval processes for nonprescription drugs other than sunscreen active ingredients under the FDA's existing time-and-extent application (TEA) process. Sunscreens and other over-the-counter (OTC) drug products that are currently marketed will not be affected by the provisions of the Act.

Background: FDA's Current OTC Ingredient Approval Process:

FDA regulates nonprescription sunscreen products as "drugs." An article that constitutes a "drug" can generally only be marketed if: (1) an applicable FDA regulation or Tentative Final Monograph (TFM)[2] has been issued that establishes the conditions under which the drug has been determined to be generally recognized as safe and effective (GRASE) or (2) FDA has approved a product-specific new drug application (NDA), or an abbreviated new drug application (ANDA).[3]

Products that are formulated and marketed for use under conditions that have been established to be GRASE under the FDA's OTC "monograph" may be marketed in the United States and are not subject to the FDA premarket clearance requirements that apply to "new drugs." The monographs are indication specific (e.g., anti-acne, anti-dandruff, analgesic), and specify the type and amount (concentration) of active ingredient(s) that must be in the finished product.

The TEA process provides one mechanism to incorporate a "new product or a product condition" in the OTC drug monograph system.[4] The TEA process is most commonly used when determining whether an active ingredient is eligible to be considered for inclusion in the OTC drug monograph system when it has been on the market in a foreign country for a minimum of five continuous years or marketed under a NDA for more than five years. If FDA determines that, based on the TEA, an ingredient is eligible to be included in the OTC monograph system, then FDA issues a public notice calling for data on the safety and efficacy of the ingredient(s). This process, however, does not currently include any statutory or regulatory deadlines for the timely review of such ingredients.

Overview of the New Sunscreen Ingredient Approval Process:

The Act amends the FDCA to provide a new, streamlined approach for reviewing new and pending applications for non-prescription sunscreen active ingredients. The last OTC sunscreen ingredient to be approved by FDA was in 1999. Since that time, eight new sunscreen applications have been filed and are still awaiting review under the TEA process.

1. ***New Application Process (Section 586C(a)):*** The Act provides a streamlined approach for FDA approving a new nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients.

   a. Submission of Request (Sections 586A and 586B(a)): Interested persons (the "sponsor") may submit a request to the FDA to determine whether a sunscreen active ingredient is GRASE ("Initial Request"). FDA must determine whether the request is eligible for further review within 60 days of the request being filed.

   b. Criteria for Eligibility (Section 586B(a)(2)): In order to be eligible for review, a nonprescription sunscreen active ingredient or ingredient blend must not currently be included in the currently stayed sunscreen monograph.[5] The ingredient must also have been used to a material extent and for a material time, as established by required information pursuant to the TEA process.[6]

   c. Public Comment (Sections 586B(a)(3) and 586B(b)(1)): If a request is eligible for further review, FDA must publish notice in on the FDA's website seeking public comment and requesting data in support of or otherwise relating to a GRASE determination, including information from the sponsor. The comment period must be no less than 45 days

   d. Filing Determination (Sections 586B(b)(2) and 586B(b)(3)): No later than 60 days after the close of the comment period, FDA must determine whether the data and other information submitted is sufficiently complete to enable FDA to conduct a substantive review and provide written notification to the sponsor and the public. If the FDA determines that the record is incomplete to make such determination, the sponsor may submit additional data and/or request a meeting with FDA.

   e. Proposed Sunscreen Order (Sections 586D(a)(1) and 586D(a)(3)): If a request is determined to be eligible for further review, FDA may convene a meeting of the Advisory Committee to review the request and data, and must issue a proposed sunscreen order within 300 days of the Initial Request. The proposed order must be published in the Federal Register and contain a tentative determination on the GRASE status of the ingredient. Interested parties will have 45 days to submit comments on the proposed sunscreen order, and the sponsor may request a meeting during this time.

   f. Final Sunscreen Order (Section 586D(a)(4)): No later than 90 days after the end of the comment period for the proposed order, the FDA must issue a final sunscreen order containing a final determination on the GRASE status of the ingredient. However, if the proposed sunscreen order had determined that the ingredient was not GRASE due to insufficient data, then the FDA must issue the final sunscreen order within 210 days after the sponsor submits any additional information requested by FDA, to allow the agency adequate time to review.

2. ***Pending Applications (Section 586C(b)):*** The Act also provides a streamlined approach

for FDA to issue final orders for applications that were pending prior to enactment of the Act. As a general rule, Sections 586A and 586B shall not apply to any pending request.

a. Proposed Sunscreen Order: For applications filed prior to the date of enactment of the Act, the FDA must complete review of the request and issue a proposed sunscreen order within 90 days of the date of enactment of the Act. If the FDA has already issued a feedback letter to the sponsor, this will be deemed a proposed sunscreen order. FDA must display the feedback letter on its website, and publish a notice of availability in the Federal Register within 45 days of the date of enactment of the Act. In either case, interested parties will have 45 days to submit comments, and the sponsor may also request a meeting during this time.

b. Final Sunscreen Order: No later than 90 days after the end of the comment period for the proposed order, the FDA must issue a final sunscreen order containing a final determination on the GRASE status of the ingredient. However, if the proposed sunscreen order determined that the ingredient was not GRASE due to insufficient data, then the FDA must issue the final sunscreen order within 210 days after the sponsor submits any additional data if an Advisory Committee is not convened, or within 270 days of submission of additional data if an Advisory Committee is convened.

3. ***Orders by the Commissioner:*** The Act also contains additional provisions that allow the Office of the Commissioner to issue a proposed sunscreen order or final sunscreen order, if the FDA does not issue such orders within the applicable timeframes.

The Act also requires the FDA to issue draft guidance within one year of the date of enactment of the Act concerning the format and content of the submissions, the data necessary to meet the safety and efficacy standard for determining whether an ingredient is GRASE, and other process requirements. FDA must also, within 5 years after the date of enactment of the Act, amend and finalize regulations under the currently stayed sunscreen OTC monograph in 21 C.F.R. Part 352. Although several versions of a final monograph for sunscreen products have been developed, no final regulations have ever been implemented.

Changes to FDA's Existing Time and Extent Application Process:

The Act also permits sponsors of eligible non-sunscreen OTC drug applications to request that the FDA provide a framework for review of their TEA application similar to the review process established for sunscreen active ingredients.

1. ***Pending TEAs:*** The Act sets forth a timeframe for the FDA to review currently pending TEAs for drugs other than nonprescription sunscreen active ingredient that were pending with FDA prior to the enactment of the Act.

a. Request for Framework for Review (Section 586F(a)): If a TEA application was pending at the FDA prior to the date of enactment of the Act, the sponsor may request the FDA to provide a "framework" for FDA's review of the application. Such request must be made within 180 days of the date of enactment of the Act, and must include the sponsor's preference as to whether the application is reviewed by FDA in accordance with: (1) the processes and procedures set forth for pending application requests under section 586C(b); (2) the current processes and procedures set forth under 21 C.F.R. Part 330; (3) an initial filing determination under the processes and procedures described in section 586B(b) and the processes and procedures set forth for pending application requests under section

586C(b); or (4) an initial filing determination under the processes and procedures described in section 586B(b) and the processes and procedures set forth under 21 C.F.R. Part 330.

b. If No Request is Made: If a sponsor does not make such request within 180 days, the application shall be reviewed by FDA in accordance with the timelines established by the applicable regulations for new TEAs when such regulations are finalized by FDA.

c. Establishing a Framework: No later than 1 year after the date of enactment of the Act, FDA must provide a framework to each sponsor that submitted a request. The framework must set forth the various timelines with respect to the processes and procedures for review of the pending TEA application.

2. ***New TEAs:*** The FDA must issue proposed regulations no later than 18 months after the date of enactment of the Act establishing timelines for the review of new applications for GRASE determinations for drugs other than nonprescription sunscreen active ingredients. The Act provides the FDA with leeway to establish such timelines, provided that such timelines are reasonable. Interested parties will have 60 days to comment on the proposed regulation. The Act also requires FDA to finalize the regulations no later than 27 months after the date of enactment of the Act.

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[1] Sunscreen Innovation Act, Pub. L. No. 113-195, 128 Stat. 2035 (2014).

[2] TFMs effectively amount to FDA advisory opinions concerning the conditions under which drugs covered by the respective TFM are generally recognized as safe and effective. FDA often cites TFMs and the conditions imposed by specific TFMs in warning letters as evidence that a drug has failed to conform to the TFM and thus constitutes a new drug. As such, companies can reasonably rely on TFMs to market nonprescription drugs, although they should be aware of the risk that FDA will alter a TFM without notice and comment rulemaking.

[3] See 21 C.F.R. Part 330.

[4] 21 C.F.R. § 330.14(c).

[5] See 21 C.F.R. Part 352.

[6] 21 C.F.R § 330.14.