Questions and Answers: FDA posts deemed final order and proposed order for over-the-counter sunscreen

On September 24, 2021, FDA took steps aimed at improving the quality, safety, and efficacy of sunscreens as part of its implementation of new authorities for certain over-the-counter (OTC) drugs. FDA posted the deemed final order for sunscreens which sets the current requirements for marketing OTC sunscreen products. FDA also posted the proposed order for sunscreens to amend and revise this deemed final order for OTC sunscreens products. The proposed order reflects FDA's proposed requirements for OTC sunscreen products for the future.

The following questions and answers provide more information on the deemed final order and proposed order.

Q. Why did the FDA issue a deemed final order for over-the-counter (OTC) sunscreen products and then issue a proposed order shortly after?

A. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law. The CARES Act includes statutory provisions to reform and modernize the way over-the-counter (OTC) monograph drugs are regulated in the United States. Specifically, the CARES Act amended the Federal Food, Drug, and Cosmetic (FD&C Act) to replace the monograph rulemaking process with an administrative order process for issuing, revising, and amending OTC monographs.

Section 505G of the FD&C Act, which was enacted by the CARES Act, created a "final administrative order" for sunscreens (the deemed final order) consisting of the requirements specified in the 1999 stayed (not in effect) final monograph for OTC sunscreen products, except for requirements governing labeling and effectiveness, which are described in a final labeling and effectiveness testing rule for sunscreens published in 2011. The CARES Act specifies that sunscreens that conform to these requirements (and to the other requirements specified by section 505G of the FD&C Act, including the general requirements for nonprescription drugs) are deemed to be GRASE and not new drugs.

The CARES Act also directs FDA to amend and revise this deemed final order for OTC sunscreens products, and requires that the proposed version of this revised sunscreen order be issued no later than 18 months after the enactment of the CARES Act (i.e., by September 27, 2021).

Q. Is the proposed order the same as the 2019 proposed rule?

A. FDA is using the proposed order as a vehicle to efficiently transition its ongoing consideration of the appropriate requirements for OTC sunscreens marketed without approved applications from the previous rulemaking process to the order process created by new section 505G of the FD&C Act. The CARES Act did not change the

scientific standards for making a GRASE determination. Because of this, the proposed order's proposals are substantively the same as those that FDA issued in the 2019 proposed rule.

Q. What is the difference between the deemed final order for OTC sunscreen products and the proposed order?

A. The deemed final order, which came into existence by operation of law on March 27, 2020 through the enactment of the CARES Act, establishes the current monograph for OTC sunscreen products. As established by the CARES Act, the deemed final order consists of the requirements in the 1999 stayed (not in effect) final monograph for OTC sunscreen products, except for labeling and testing requirements, which are described in a final labeling and effectiveness testing rule for sunscreens published in 2011. FDA believes that most sunscreens on the market are in compliance with this order.

The proposed order sets out FDA's proposed revisions to this deemed final order and therefore reflects FDA's proposed requirements for OTC sunscreen products for the future.

Q. When will the proposed order be in effect?

A. The proposed order is a proposal and does not "take effect" until it is finalized. A 45-day public comment period began when FDA issued the proposed order. After reviewing and considering the comments, FDA will issue a final order that will include an effective date. The CARES Act specifies that the effective date for the final order cannot be earlier than one year after issuance of the final order.

Q. Why did FDA withdraw its Enforcement Policy — OTC Sunscreen Drug Products Marketed Without an Approved Application guidance?

A. Because the 1999 final sunscreen monograph was stayed before it could go into effect, FDA issued the *Enforcement Policy — OTC Sunscreen Drug Products Marketed Without an Approved Application*, which set forth an enforcement discretion policy regarding sunscreen products marketed without an approved application. Once the CARES Act established the requirements for legally marketing a sunscreen product without an approved application (which are set forth in 505G of the FD&C Act and the deemed final order), this enforcement policy was no longer needed and therefore withdrawn.

Q. What are the differences in the requirements between the deemed final order for OTC sunscreen products and the proposed order?

A. The requirements of the deemed final order are those set forth in the 1999 stayed (not in effect) final sunscreen monograph, except for the requirements governing labeling and effectiveness, which are described in a final 2011 labeling and effectiveness testing rule. These requirements largely correspond to the conditions under which sunscreens that do not have approved NDAs were marketed prior to the enactment of the CARES Act. In contrast, the proposed order, which proposes to amend the sunscreens monograph embodied in the deemed final order, reflects

proposals for future requirements (that were also set forth in the 2019 proposed rule). Thus, there are a number of differences between the two orders.

Some differences between the deemed final order and the proposed order include:

- **Maximum SPFs:** The deemed final order for sunscreens established by the CARES Act does not include a limit on maximum SPF values. The proposed order proposes that the maximum labeled SPF value should be SPF 60+. While the proposed maximum labeled SPF value is 60+, the proposed order permits the marketing of sunscreen products formulated with SPF values up to 80.
- **Active ingredients:** The deemed final order considers sunscreens containing 16 sunscreen active ingredients to be GRASE, consistent with the 1999 stayed (not in effect) sunscreen monograph. Based on new data and changed conditions since issuance of the 1999 monograph, the proposed order proposes GRASE status for sunscreens containing zinc oxide and titanium dioxide; not GRASE status for sunscreens containing aminobenzoic acid (PABA) and trolamine salicylate, because the evidence shows that these sunscreens are not GRASE due to safety issues; and not GRASE status for sunscreens containing cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, and avobenzone, because additional data is needed to show that these sunscreens are GRASE.
- **Broad spectrum requirements:** Consistent with the requirements in a labeling and effectiveness rule for sunscreens issued in 2011, the deemed final order does not require broad spectrum testing, but creates an optional broad spectrum labeling claim and broad spectrum testing that is required for inclusion of this claim on labeling. To address the growing evidence of significant harms associated with UVA exposure, the proposed order proposes a requirement that all sunscreens with SPF values of 15 and above satisfy broad spectrum requirements, including a proposed new requirement that broad spectrum products meet a UVA I / UV ratio of 0.7 or higher.
- **Dosage forms:** The deemed final order does not address the GRASE status of sunscreens in specific dosage forms. By operation of a separate section of the CARES Act, sunscreens in dosage forms other than oils, lotions, creams, gels, butters, pastes, ointments, sticks, sprays, or powders, require an approved application to be marketed. The proposed order proposes the following dosage forms as GRASE for use in sunscreens: oils, lotions, creams, gels, butters, pastes, ointments, and sticks. FDA proposes GRASE status for spray sunscreens, subject to testing and labeling requirements, and proposes that additional data are needed to determine that powders are GRASE.
- **Labeling:** The deemed final order contains the same labeling requirements that have been in effect for sunscreen products since 2011. In the proposed order, FDA has proposed adding certain information to the main part of the product label, including an alphabetical listing of the sunscreen active ingredients in the product, followed by "Sunscreen" and the product's dosage form (such as lotion or spray). Also, for sunscreen products that have not been shown to help prevent skin cancer or early skin aging caused by the sun, the SPF statement on the main part of the product label would be followed by an asterisk (*) directing consumers to see the "Skin Cancer/Skin Aging alert" elsewhere on the label.
- **Final formulation testing and recordkeeping:** The deemed final order does not address record keeping. The proposed order requires 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. In addition, we are proposing to require responsible persons to keep records of sunscreen formulation testing, and we are clarifying that required records would be subject to FDA inspection.
- **Sunscreen-insect repellent combinations:** The deemed final order does not address sunscreen-insect repellent combinations. The proposed order proposes to classify these products as not GRASE 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.

Q. When will the proposed order for OTC sunscreen products become a final order?

A. The CARES Act does not establish a deadline for finalization of the proposed order. It does specify, however, that a final order cannot go into effect sooner than one year after issuance of the final order. When issued, any final order will include information regarding implementation and the effective date.

Q. Can the public comment on the deemed final order?

A. There is no comment period for the deemed final order, as the order was established legislatively by operation of the CARES Act. However, questions regarding this or other deemed final orders may be submitted to druginfo@fda.hhs.gov.

Q. Can the public comment on the proposed order? Why didn't the FDA respond to comments received for the 2019 proposed rule in the proposed order?

A. There is a 45-day comment period for the proposed order. The comment period affords an opportunity for the public to submit information that has become available since the closure of the comment period on the 2019 proposed rule.

FDA is using this proposed order to efficiently transition its ongoing consideration of the appropriate requirements for OTC sunscreens marketed without approved applications from the previous rulemaking process to the order process created by new section 505G of the FD&C Act. We will consider all comments that were submitted to the public docket for the 2019 proposed rule within its comment period to be constructively submitted as comments on this proposed order. To enable the agency to review and address these comments (and new comments that may be submitted on this proposed order) as expeditiously as possible, FDA asks commenters **not** to re-submit comments that were already submitted in a timely fashion to the 2019 proposed rule. FDA believes that this approach will allow us to efficiently consider public input as the agency assesses the appropriate regulatory requirements for OTC sunscreens marketed without approved applications.

Q. How can I view the deemed final order and the proposed order?

A. Administrative orders are posted on FDA's new web portal for monograph reform, OTC Monographs@FDA. OTC Monographs@FDA allows FDA to post final and proposed administrative orders. Because the sunscreen docket at www.regulations.gov (FDA-1978-N-0018) contains the many comments that were submitted on the 2019 proposed rule and are being considered constructively submitted to the proposed order, FDA will also be posting the proposed order at www.regulations.gov. New comments on the proposed order should be submitted through www.regulations.gov following the instructions on how to submit comments provided in the Notice of Availability announcing the proposed order.

Q. What is FDA proposing for sunscreen active ingredients in the proposed order?

A. To establish a final order for sunscreens, FDA is reviewing the active ingredients in these products to determine whether sunscreens with such ingredients are

generally recognized as safe and effective (GRASE) for OTC sunscreen use. This proposed order applies only to sunscreen active ingredients listed in the 1999 stayed (not in effect) final monograph. FDA is proposing the following categories of sunscreen ingredients:

GRASE* for use in sunscreens	Not GRASE for use in sunscreens because of safety concerns	Not GRASE for use in sunscreens because additional data needed
Zinc oxide and titanium dioxide	Aminobenzoic acid (PABA) and trolamine salicylate	Cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone, avobenzone

*GRASE= Generally Recognized as Safe and Effective, when also in conformity with all other applicable requirements.

Q: Why are titanium dioxide and zinc oxide the only proposed GRASE ingredients?

A. FDA's review of publicly available evidence has found sufficient safety data on both zinc oxide and titanium dioxide to support a proposal that sunscreen products containing these ingredients (at concentrations of up to 25%) are GRASE.

Our evaluation of the available safety data for aminobenzoic acid (PABA) and trolamine salicylate, however (neither of which is used in marketed sunscreens any longer), has caused us to tentatively conclude that the risks associated with use of these active ingredients in sunscreen products outweigh their benefits. In the case of trolamine salicylate, these risks include the potential for serious bleeding and salicylate toxicity (vomiting, hyperventilation, metabolic disturbances, coma and death) when this ingredient is used in sunscreens. For PABA, the risks include significant rates of allergic and photoallergic skin reactions, as well as cross-sensitization with structurally similar compounds that may lead to allergies to commonly used medications. Accordingly, we are proposing that these two ingredients are not GRASE for use in sunscreens.

Because the public record does not currently contain sufficient data to support positive GRASE determinations for cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone or avobenzone, we are proposing that these ingredients are not GRASE because they require additional data.

Q: FDA is asking for safety data on 12 active ingredients that will take a long time to gather. What will the next steps be for issuing further final or proposed orders based on the data?

A: FDA is committed to working with industry and public health stakeholders to help ensure that the sunscreens consumers use every day on themselves and their families are safe and effective for daily, life-long use. The comment period on this proposed order affords an opportunity for the public to submit information that has become

available since the closure of the comment period on the 2019 proposed rule. This includes information that has become available regarding the eight sunscreen active ingredients that, in the pre-CARES rulemaking context, were the subject of timely requests for deferral in order to conduct studies to generate data first identified as lacking in the 2019 proposed rule.

However, if at the close of the comment period on this proposed order, the available data do not resolve the outstanding questions about each of these ingredients, but the agency has received satisfactory indication of timely and diligent progress on the necessary studies for a specific ingredient, FDA would be prepared to initially defer issuance of a revised final order on the GRASE status of sunscreens containing that particular active ingredient. Such a deferral would be for a period of not more than one year, with a possibility of extension depending on further satisfactory progress with the studies. However, if, in FDA's judgment, studies for any active ingredient do not appear to be proceeding in a timely manner or otherwise do not appear to be productive, the agency expects that it will proceed to a revised final order on sunscreens containing this ingredient after this initial deferral. FDA will determine whether the sum of the data, if timely submitted, is likely to be adequate to provide all the data that are necessary to make a determination of general recognition of safety and effectiveness.

To finalize the GRASE determinations for OTC sunscreen products containing these active ingredients, the agency will continue to utilize the administrative order process required by the CARES Act.

Q: Should consumers only use sunscreens with zinc oxide and/or titanium dioxide?

A: This proposed order does not represent a conclusion by the FDA that the sunscreen active ingredients proposed as having insufficient data are unsafe for use in sunscreens. Rather, we are requesting additional information on these ingredients so that we can evaluate their GRASE status in light of changed conditions, including substantially increased sunscreen usage and evolving information about the potential risks associated with these products since they were originally evaluated.

Sun safety is important for everyone and all skin tones, and consumers can reduce risks from sun exposure with continued use of sun protection measures, including sunscreen. Broad Spectrum sunscreens with SPF values of at least 15 are only one element of a skin-cancer prevention strategy that should also include other sun protective behaviors such as wearing protective clothing that adequately covers the arms, torso, and legs; wearing sunglasses and a hat that provides adequate shade to the whole head; and seeking shade whenever possible during periods of peak sunlight. Medical authorities such as the Centers for Disease Control and Prevention, the American Academy of Dermatology, and major physicians' associations endorse similar recommendations. More about sun protection and sunscreens can be found on the FDA website. Pregnant women and persons concerned about using sunscreens on infants or children are encouraged to consult their health care professional.

Q: Why is FDA proposing changes to the maximum SPF level shown on sunscreen labels in the proposed order?

A: FDA had previously proposed (in 2011) that the maximum permissible labeled SPF value should be SPF 50+.

Since 2011, evidence shows additional meaningful clinical benefit associated with broad spectrum sunscreen products with an SPF up to 60. For this reason, the agency proposes that the maximum labeled SPF value should be SPF 60+ rather than 50+. While the proposed maximum labeled SPF value is 60+, we are proposing to permit the marketing of sunscreen products formulated with SPF values up to 80. We hope this formulation margin will (1) help facilitate the development of products with greater UVA protection and (2) more fully account for the range of variability in SPF test results (discussed in more detail in the proposed order).

Q: Are there any changes to labeling of sunscreens in the proposed order?

A: FDA's labeling proposals were informed by published scientific studies on consumer behavior and choice of sunscreens. These studies show that many consumers do not turn a sunscreen bottle around to read the Drug Facts section of the label, which is currently where the active ingredients and Skin Cancer/Skin Aging alert warning appear. Because FDA wants to ensure that consumers are aware of critical information about the protections that are (or are not) provided by sunscreen products and can readily evaluate and compare sunscreen products before purchasing, FDA has proposed adding certain information to the main portion of the product label.

Currently, most OTC drug products list the active ingredients in the product on the principal display panel (the label panel that is most prominent and is visible on the retail shelf). This proposed change in the labeling for sunscreens brings sunscreens in line with most other OTC drug products.

Q: How would the proposed labeling requirements in the proposed order benefit consumers?

A. FDA believes that the proposed modifications to the principal display panel will improve consumer awareness of important information on sunscreen labels. These proposed changes include:

- The addition of an alphabetical listing of the sunscreen active ingredients in the product, followed by "Sunscreen" and the product's dosage form (such as lotion or spray).
- For sunscreen products that have not been shown to help prevent skin cancer or early skin aging caused by the sun, the SPF statement would be followed by an asterisk (*) directing consumers to see the "Skin Cancer/Skin Aging alert" elsewhere in the label.
- To prevent required information from being obscured or overwhelmed by other labeling features, we are revising the format requirements for the SPF, broad spectrum, and water resistance statements on the label.

Q: How does the deemed final order impact the existing sunscreen products on the market?

A. Under the provisions of section 505G as added by the CARES Act, sunscreens that conform to the requirements in the deemed final order and all other applicable requirements are deemed to be GRASE and not new drugs. Until FDA finalizes its

order proposing to revise the deemed final order, sunscreen manufacturers are required to follow the requirements in the deemed final order to market a sunscreen product without an approved application. If manufacturers do not comply with the deemed final order and all other applicable requirements, the FDA's responses may include issuing a warning letter to the company, or seeking an injunction, seizure, or consent decree.

Q: How does this proposed order impact the existing sunscreen products on the market?

A. The proposed order does not require any sunscreen products to be removed from the market. Instead, it requests manufacturers who want to continue marketing sunscreen products containing active ingredients for which insufficient data exist, along with other interested parties, to provide FDA with additional data on the active ingredients' safety. Once a final order or orders are issued addressing a particular active ingredient, companies will only be able to continue marketing sunscreens with that active ingredient if FDA has determined the active ingredient be GRASE for use in sunscreens, unless they first seek FDA approval.