

Over-the-Counter (OTC) Monograph Reform: OTC Sunscreen Drugs

Steven Adah, Ph.D

Associate Director of Monographs

Office of Nonprescription Drugs
Center for Drug Evaluation and Research, FDA

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Objectives

- Provide an overview of OTC sunscreen drugs
- Discuss the relevant regulatory history for OTC sunscreen drugs prior to CARES Act
- Provide an overview of OTC Monograph Reform
- Provide a general overview of Deemed Final Orders (DFOs) for OTC monographs
- Discuss the DFO for OTC sunscreen drugs
- Discuss the Proposed Order for OTC sunscreen drugs

Overview of OTC Sunscreen Drugs

- Uses
 - All sunscreen drugs: help prevent sunburn
 - For **broad spectrum** sunscreen products with a sun protection factor (SPF) value of 15 or higher when used as directed with other sun protection measures: decrease the risk of skin cancer and early skin aging caused by the sun
- Topically applied
- Active ingredients in sunscreen drugs absorb, reflect, and/or scatter radiation in the UV range

Regulatory Pathways for Marketing OTC Sunscreen Drugs



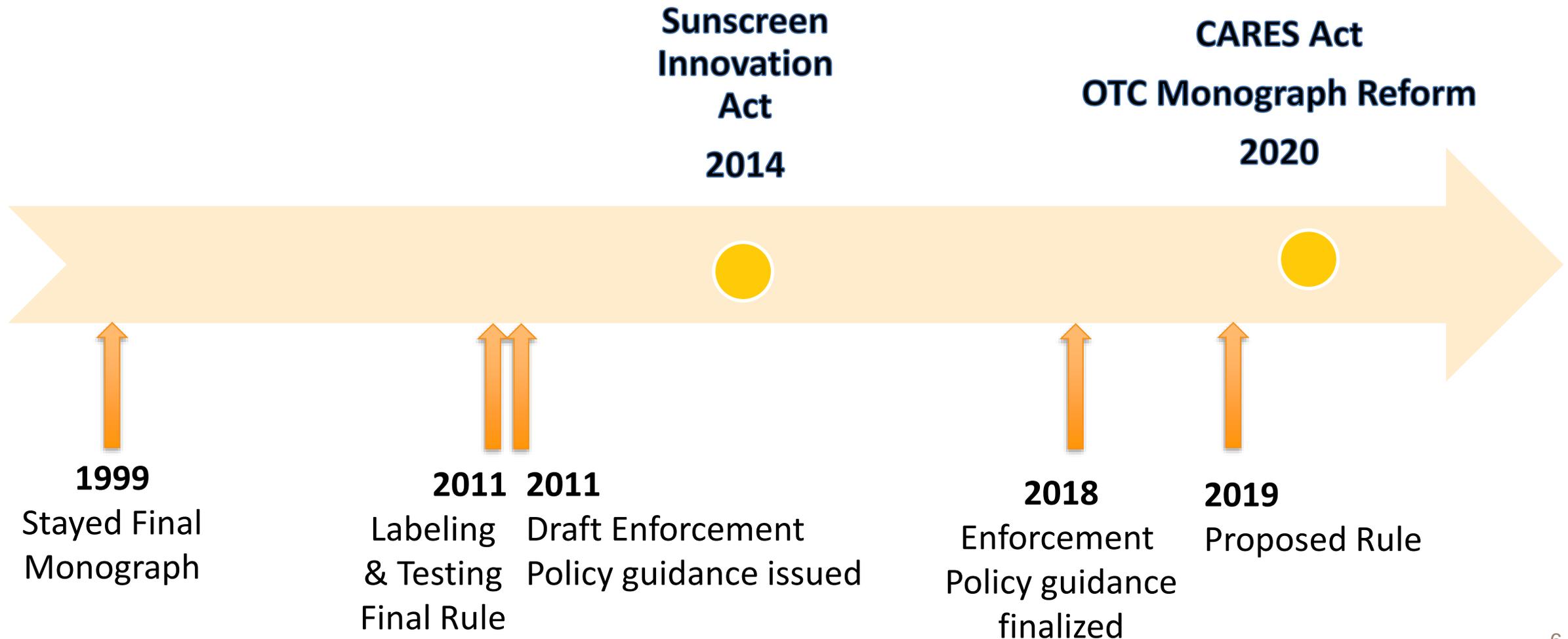
- New Drug Application/Abbreviated New Drug (NDA/ANDA)
 - Application submitted to FDA for premarket approval
- OTC Drug Review (OTC Monograph)
 - Allows for certain OTC drugs to be marketed without an approved drug application if the drug **follows the requirements in the applicable monograph(s) and** complies with statutory and regulatory requirements
 - Began as a rulemaking process in 1972 to evaluate the safety and effectiveness of OTC drug products marketed in the United States before May 11, 1972
 - Established conditions under which an OTC drug is generally recognized as safe and effective (GRASE) in the form of OTC monographs, which were embodied in regulations

Regulatory Pathways for Marketing OTC Sunscreen Drugs (cont'd)



- Since enactment of the CARES Act on March 27, 2020, the monograph system has become an administrative order process
 - OTC monographs that used to be in the form of regulations are now deemed to be administrative orders. FDA can update these orders and establish new ones via a new administrative order process
 - OTC drugs marketed under the revamped monograph system are now subject to new statutory requirements, which include compliance with any applicable monograph order

Regulatory History for OTC Sunscreen Drugs: Abbreviated Timeline





ENACTMENT OF CARES ACT

Path forward for OTC Monograph Sunscreen Drug Products

OTC Monograph Reform

- On March 27, 2020, the “Coronavirus Aid, Relief, and Economic Security Act” (CARES Act) was enacted
- Includes important statutory provisions that reform and modernize the way OTC monograph drugs are regulated in the United States
 - Replaces the rulemaking process with an administrative order process to establish, revise, or amend OTC monographs
- Grants FDA the authority to assess and collect fees from regulated industry



OTC Monograph Reform: Sunscreen Provisions



- CARES Act includes provisions that address OTC sunscreen drugs specifically
 - Set specific requirements for OTC sunscreen drugs marketed without an NDA to be deemed GRASE and not a new drug.
 - Required FDA to issue a **proposed** revised sunscreen administrative order not later than 18 months after the enactment of the CARES Act (i.e., by September 27, 2021).
 - FDA posted the deemed final order (DFO) containing the GRASE requirements for OTC sunscreen drugs, and the proposed sunscreen administrative order on September 24, 2021.

DEEMED FINAL ORDER (DFO) FOR OTC SUNSCREEN DRUGS

DFOs for OTC Monographs

- Established by CARES Act; effective March 27, 2020
- Provide the current OTC monograph conditions in effect for each therapeutic category
 - Include drugs in Final Monograph regulations and Category I drugs subject to a TFM that is the most recently applicable proposal/determination
 - Does not include Category I drugs subject to an ANPR or Category III drugs subject to a TFM

DFO for OTC Sunscreen Drugs

- OTC Monograph M020: Sunscreen Drug Products for OTC Human Use is the final order as deemed by section 505G(b)(8) and 505G(k)(2)(B) of the FD&C Act
- Incorporates:
 - The final OTC monograph requirements from 21 CFR part 352 (as published on May 21, 1999) except for
 - Labeling and effectiveness requirements, which come from 21 CFR 201.327 (as in effect on March 26, 2020)
- Essentially preserves the pre-CARES status quo marketing conditions for sunscreens marketed without an approved drug application
- Note that, separate from the DFO, by operation of section 505G(m)(2) of the FD&C Act, sunscreens in all dosage forms other than oil, lotion, cream, gel, butter, paste, ointment, stick, spray, and powder require an NDA or ANDA.
- Requirements remain in effect until the FDA issues another final order revising the DFO

Availability of DFO for OTC Sunscreen Drugs



- FDA is posting the DFOs on the web:
 - On September 20, 2021, FDA published a notice announcing the availability of certain DFOs
 - On September 24, 2021, FDA posted the DFO for OTC sunscreen drugs in the new web portal at [OTC Monographs@FDA](https://www.fda.gov/oc/otc-monographs)
- FDA withdrew the sunscreen enforcement policy guidance in conjunction with the posting of the DFO for OTC sunscreen drugs

PROPOSED ORDER FOR OTC SUNSCREEN DRUGS

Issuance of Proposed Order for OTC Sunscreen Drugs



- On September 24, 2021, FDA issued a proposed order to amend and revise the DFO for OTC sunscreen drugs
- Efficiently transitions FDA's ongoing consideration of the appropriate requirements for OTC sunscreen drugs marketed without approved applications from the previous rulemaking process to the administrative order process
- Proposed requirements are substantively the same as those described in the 2019 Proposed Rule with minor changes
 - CARES Act did not change the legal and scientific standards for making a GRASE determination

Proposed Order for OTC Sunscreen Drugs

- This proposed order, if finalized, would:
 - Replace the DFO in its entirety with new conditions under which OTC sunscreen drugs would be determined to be GRASE
 - Set forth certain characteristics that would establish that an OTC sunscreen drug is not GRASE
- The proposed order is a proposal and does not take effect until FDA finalizes it

Summary of Differences

	DFO	Proposed Order proposes that:
<p>Active Ingredients</p> 	<p>Considers sunscreens containing any of the 16 sunscreen active ingredients in the DFO to be GRASE</p>	<ul style="list-style-type: none"> • GRASE for use in sunscreens <ul style="list-style-type: none"> ○ zinc oxide and titanium dioxide • Not GRASE for use in sunscreens because of safety concerns <ul style="list-style-type: none"> ○ aminobenzoic acid (PABA) and trolamine salicylate • Not GRASE for use in sunscreens because additional data needed: <ul style="list-style-type: none"> ○ cinoxate, dioxybenzone, ensulizole*, homosalate*, meradimate*, octinoxate*, octisalate*, octocrylene*, padimate O, sulisobenzone, oxybenzone*, and avobenzone*

*Ingredients for which FDA received a timely request for deferral of rulemaking after the 2019 proposed rule so that manufacturers could provide necessary data.

Summary of Differences (cont'd)

	DFO	Proposed Order proposes that:																				
<p>Maximum SPF</p> 	<p>Does not include a limit on maximum SPF values</p> <p>SPF labeling same as tested results</p>	<p>Maximum labeled SPF value = SPF 60+</p> <ul style="list-style-type: none"> permits the marketing of sunscreen products formulated with SPF values up to 80 <p>SPF labeling using lowest number in a range of tested results</p> <table border="1"> <thead> <tr> <th>Determined SPF</th> <th>Labeled SPF</th> <th>Determined SPF</th> <th>Labeled SPF</th> </tr> </thead> <tbody> <tr> <td>2-14</td> <td>Determined SPF</td> <td>30-39</td> <td>30</td> </tr> <tr> <td>15-19</td> <td>15</td> <td>40-49</td> <td>40</td> </tr> <tr> <td>20-24</td> <td>20</td> <td>50-59</td> <td>50</td> </tr> <tr> <td>25-29</td> <td>25</td> <td>60-80</td> <td>60+</td> </tr> </tbody> </table>	Determined SPF	Labeled SPF	Determined SPF	Labeled SPF	2-14	Determined SPF	30-39	30	15-19	15	40-49	40	20-24	20	50-59	50	25-29	25	60-80	60+
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Summary of Differences (cont'd)



	DFO	Proposed Order proposes that:
Broad Spectrum Requirements 	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	All sunscreens with SPF values of 15 and above must satisfy broad spectrum requirements, including a proposed new requirement that broad spectrum products meet a UVA I / UV ratio of 0.7 or higher

Summary of Differences (cont'd)

	DFO	Proposed Order proposes that:
<p data-bbox="104 411 308 534">Dosage Forms</p> 	<p data-bbox="372 411 1116 1368">The DFO itself does not address the GRASE status of sunscreens in specific dosage forms. However, by operation of section 505G(m)(2) of the FD&C Act, sunscreens in all dosage forms other than oil, lotion cream, gel, butter, paste, ointment, stick, spray, and powder can only be marketed with an NDA or ANDA.</p>	<ul data-bbox="1166 411 2423 1382" style="list-style-type: none"> • <u>GRASE dosage forms for sunscreens</u> <ul style="list-style-type: none"> ○ Oils, lotions, creams, gels, butters, pastes, ointments, and sticks ○ Sprays (subject to particle size restrictions; flammability testing; and related safety labeling requirements) • <u>Not GRASE for sunscreens due to insufficient data</u> <ul style="list-style-type: none"> ○ Powders • Does not propose to change the new drug status of sunscreens in all other dosage forms

Summary of Differences (cont'd)

	DFO	Proposed Order proposes that:
<p>Principal Display Panel (PDP) Labeling</p> 	<p>Same labeling requirements that have been in effect for sunscreen products since 2011</p>	<ul style="list-style-type: none"> • Revised Statement of Identity (SOI) <ul style="list-style-type: none"> ○ Alphabetical listing of active ingredients followed by “Sunscreen” and the product’s dosage form • Sunscreens with an SPF below 15 required to include the SPF statement on PDP followed by an asterisk(*) to a statement directing consumers to see the “Skin Cancer/Skin Aging alert” in the Drug Facts label (DFL) • Font and placement changes to ensure SPF, broad spectrum, and water resistance statements stand out

Summary of Differences (cont'd)

	DFO	Proposed Order proposes that:
<p>Final formulation testing and recordkeeping</p>  	<p>Does not address recordkeeping</p>	<ul style="list-style-type: none"> • Records of required final formulation testing of sunscreen products be maintained for 1 year after the product expiration date, or, if the product is exempt from expiration dating (as most sunscreens are), for 3 years after distribution of the last lot labeled in reliance on that testing • Responsible persons keep records of sunscreen formulation testing • Clarifies that required records would be subject to FDA inspection

Summary of Differences (cont'd)

	DFO	Proposed Order proposes that:
<p>Sunscreen-insect repellent combinations</p> 	<p>Does not address sunscreen-insect repellent combinations</p>	<ul style="list-style-type: none"> • These products are 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

Seeking Information

- Proposed order does not represent a conclusion by FDA that the 12 sunscreen active ingredients proposed as needing additional data are unsafe for use in OTC sunscreen drugs
- FDA requested additional information on these active ingredients so that we can evaluate their GRASE status considering changed conditions of use such as:
 - substantially increased sunscreen drug usage and exposure to sunscreens by consumers
 - evolving information about their potential risks

Comment Period on Proposed Order

- Public comment period ends December 27, 2021
 - Afforded an opportunity for the public to submit information that has become available since the closure of the comment period for the 2019 Proposed Rule
 - FDA will consider timely comments on the 2019 proposed rule to be constructively submitted to the proposed order

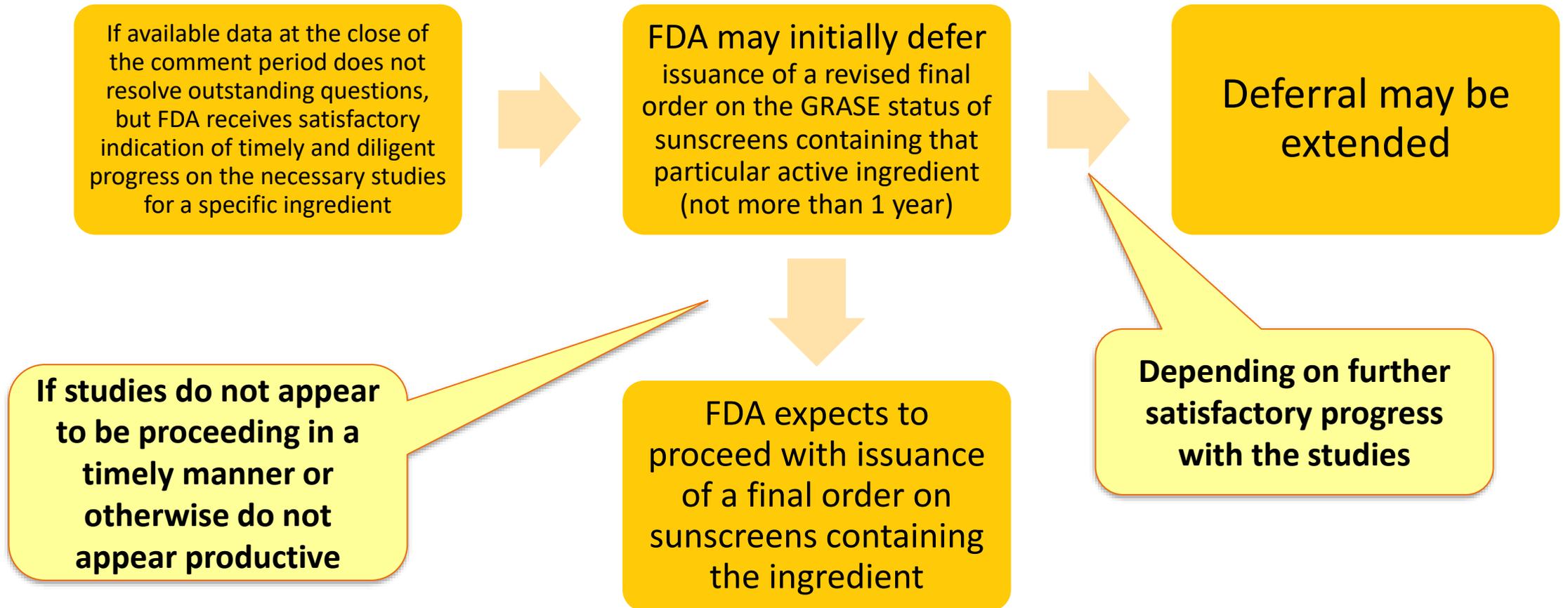
Finalizing Proposed Order

- After reviewing and considering the comments, FDA will issue a final order
 - By law, effective date of that order will not be earlier than one year after the agency issues the final order

Deferral of Issuance of Final Order on the GRASE Status of Sunscreens Containing a Particular Active Ingredient

- If at any time the available evidence becomes sufficient to resolve the uncertainty as to the GRASE status of any of the 12 sunscreen active ingredients that we have requested more data for, FDA intends to issue a final order on the ingredient
- But the Agency may defer issuance of a revised final order on the GRASE status of sunscreens containing one of these ingredients if we see progress on development of needed data (see next slide for the conditions under which FDA would be prepared to defer)

Considerations for Deferring Issuance of a Final Order on the GRASE Status of Sunscreens Containing One of 12 Active Ingredients



Sun Safety for Consumers

- Sun safety is important for everyone, regardless of skin tone
- Americans can reduce risks from sun exposure with continued use of sun protection measures including broad spectrum sunscreen with SPF values of at least 15



Contact Us

- For questions on the deemed final order (DFO) and proposed order for OTC sunscreen drugs, email FDA at druginfo@fda.hhs.gov
- Additional Questions:
 - OTC Monograph Reform druginfo@fda.hhs.gov
 - User fees (OMUFA) CDERCollections@fda.hhs.gov
 - Meeting requests monograph-meeting-requests@fda.hhs.gov
 - Small business and industry assistance cdersbia@fda.hhs.gov

Resources

- Deemed Final Order for OTC Sunscreens - [Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use](#)
- Proposed Order for OTC Sunscreens - [Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use](#)
- OTC Monographs@FDA - <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>
- FDA's OTC Drug Review | OTC Monograph Reform in the CARES Act website
<https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act>
- Additional Webinars on OTC Monograph Reform
 - For Topic, select 'OTC Drug Regulation'<https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/cder-small-business-and-industry-assistance-sbia-learn>

