Sunscreen Innovation Act Stakeholder Meeting

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Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration (FDA)

February 4, 2015

Outline

- Monograph amendments prior to SIA
- Sunscreen Innovation Act (SIA)
  - What the Act does NOT do
  - What the Act does (statutory requirements)
  - Process for review of requests under SIA
  - What is required from industry
- SIA and monograph reform
- Summary and next steps

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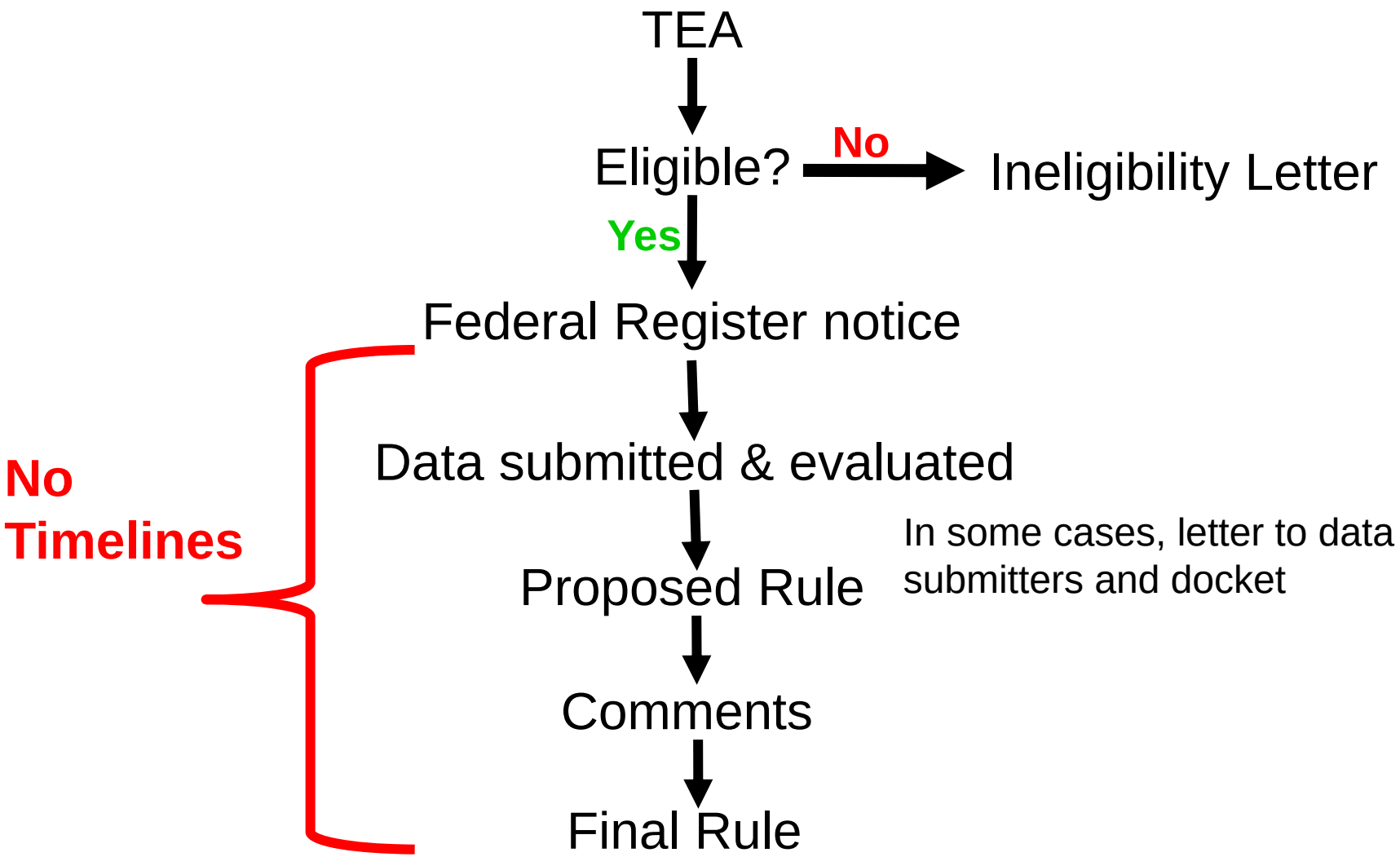
Monograph Amendment Processes

- Process of finalizing monographs ongoing
- FDA can initiate a change through rulemaking
  - Safety
  - Effectiveness
- Citizen Petition requesting change
- Time and Extent Application (TEA)
  - A process in which a new condition is added to an existing monograph

Time and Extent Application

- Process allows active ingredients that meet certain conditions for duration and extent of marketing to be considered for inclusion in the monograph
- In addition to active ingredients, other ‘conditions’ may be considered under TEAs (dosage forms, dosage strength or route of administration)
- TEA process regulations established in 2002 (21 CFR 330.14)
- Must have been marketed to a material extent and for a material time

Time and Extent Application (TEA) Process Before SIA



Current TEA Submissions

- Submitted 2002-2009
  - None have been added to any monograph
- Sunscreens (8)
  - All eligible for TEA and FR notices issued
  - 6 feedback letters issued→ **Proposed Orders Jan 6, 2016** 
  - Proposed Orders pending for other 2→ **Feb 24, 2015**
- Nonsunscreen TEAs (6)
  - Eligible: dandruff (3; 1 no data), 1 laxative, 1 acne, 1 gingivitis
- No new eligibility determinations since SIA

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Sunscreen Innovation Act

P.L. 113-195

- Enacted November 26, 2014
- Goal
  - to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients
  - and for other purposes (nonsunscreen TEAs)
- 6-year sunset provision for timelines for new requests but not for the new sunscreen TEA order process

What SIA Does NOT Do

- Guarantee new sunscreen ingredients will be on the market by this summer
  - If additional data are needed, timelines for FDA actions are triggered by industry's submission of required data
- Change Generally Recognized as Safe and Effective (GRASE) standards
- Change FDA's scientific review
- Change rulemaking process for monographs or the overall monograph system
- Provide additional FDA resources for monograph, TEA, or SIA review

What the SIA Does
Statutory Requirements

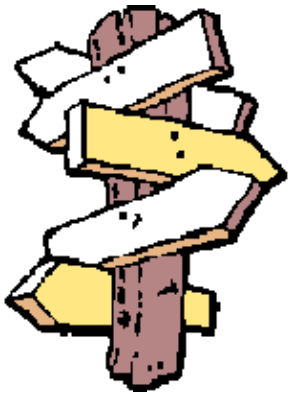
- Sunscreens
  - New process for review of active ingredients
    - Defined review timelines
    - Commissioner issues orders if timelines not met
    - Administrative orders
  - Requires publication of guidances
  - Requires rulemaking
- Nonsunscreen
  - Provides additional framework for pending TEAs: administrative orders or rulemaking
  - Requires rulemaking to establish timelines
- Government Accountability Office (GAO) and FDA reports to Congress

Sunscreen Review Process

- Changes rulemaking process to orders
- Sunscreen orders
  - Applies only to nonprescription sunscreen active ingredients
  - Mandatory FDA review timelines
  - Format and content requirements for new requests
  - FDA can refuse to file a deficient application
  - Provides for public notice and comment
  - Advisory committees may be convened during review
  - Ingredients FDA finds GRASE can be marketed under terms of Final Orders

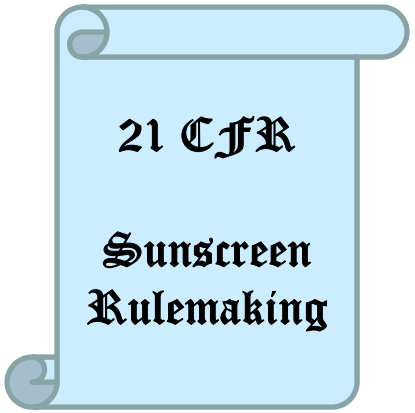
SIA Sunscreen Guidances

- Four FDA Guidances for Industry
  - Application format and content, criteria for refuse to file
  - Safety and efficacy data requirements
  - Withdrawal of request
  - Use of advisory committees
- Timelines
  - Draft guidances must publish within 1 year [November 26, 2015]
  - Final guidances must publish within 2 years [November 26, 2016]



SIA Sunscreen Rulemakings

- Final regulations on sunscreen monograph must be finalized within 5 years [November 26, 2019]
- If the regulations do not include SPF and dosage forms, FDA must report to Congress on the reasons why not and include a plan to address in rulemaking

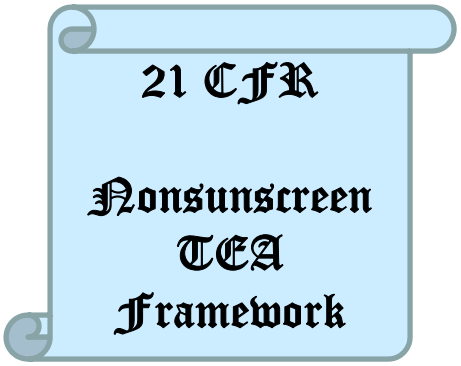


Nonsunscreen TEA Process Pending Applications

- Sponsor to request framework within 180 days of enactment and include a preferred review process [May 25, 2015]
  - SIA order process without filing requirements
  - Rulemaking process without filing requirements
  - SIA order process with filing requirements
  - Rulemaking process with filing requirements
- FDA to provide timelines for review by 1 year [November 26, 2015]

Nonsunscreen Rulemakings

- Proposed Rule on framework for review of nonsunscreen TEAs→ issue by 18 months [May 26, 2016]
- 60 day comment period
- Final Rule by 27 months [February 26, 2017]
- Rules must include timelines for review



Timelines for Nonsunscreen TEAs

- Rule must establish timelines for pending and new nonsunscreen requests
- Must
  - Reflect FDA's public health priorities
  - Consider FDA resources
  - Be reasonable
- May be different depending on the application
- Do not have to be the same as for sunscreens

Reports to Congress

- GAO
  - **3 years:** SIA metrics, use of advisory committees, and impact on other OTC drug review
  - **5.5 years:** Update on these and other aspects of OTC program
- FDA
  - **18 months:** Letter on review of pending nonsunscreen TEAs
  - **18 months, 3.5 years, 4.5 years:** SIA metrics including staffing and costs, and recommendations for process improvements

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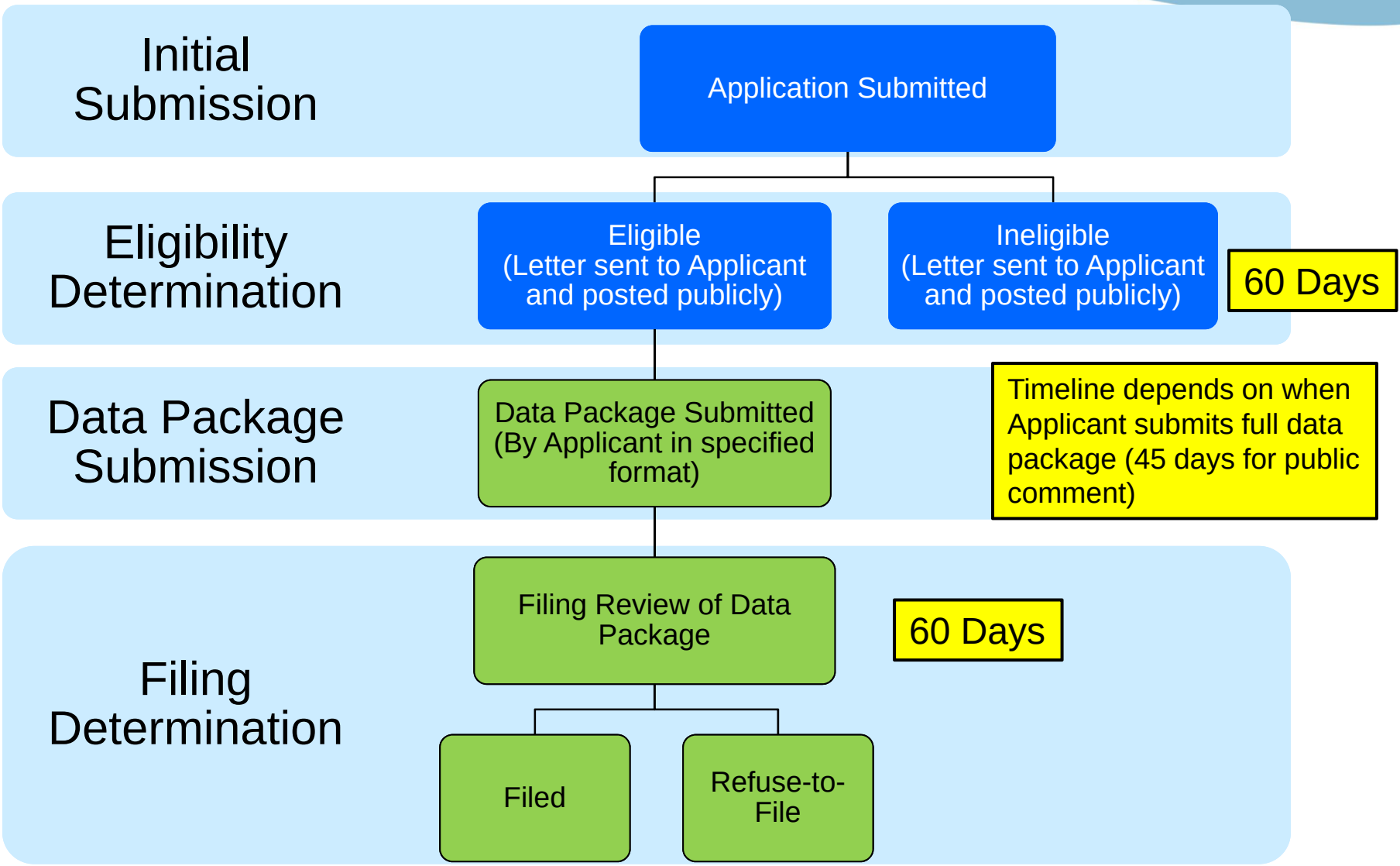
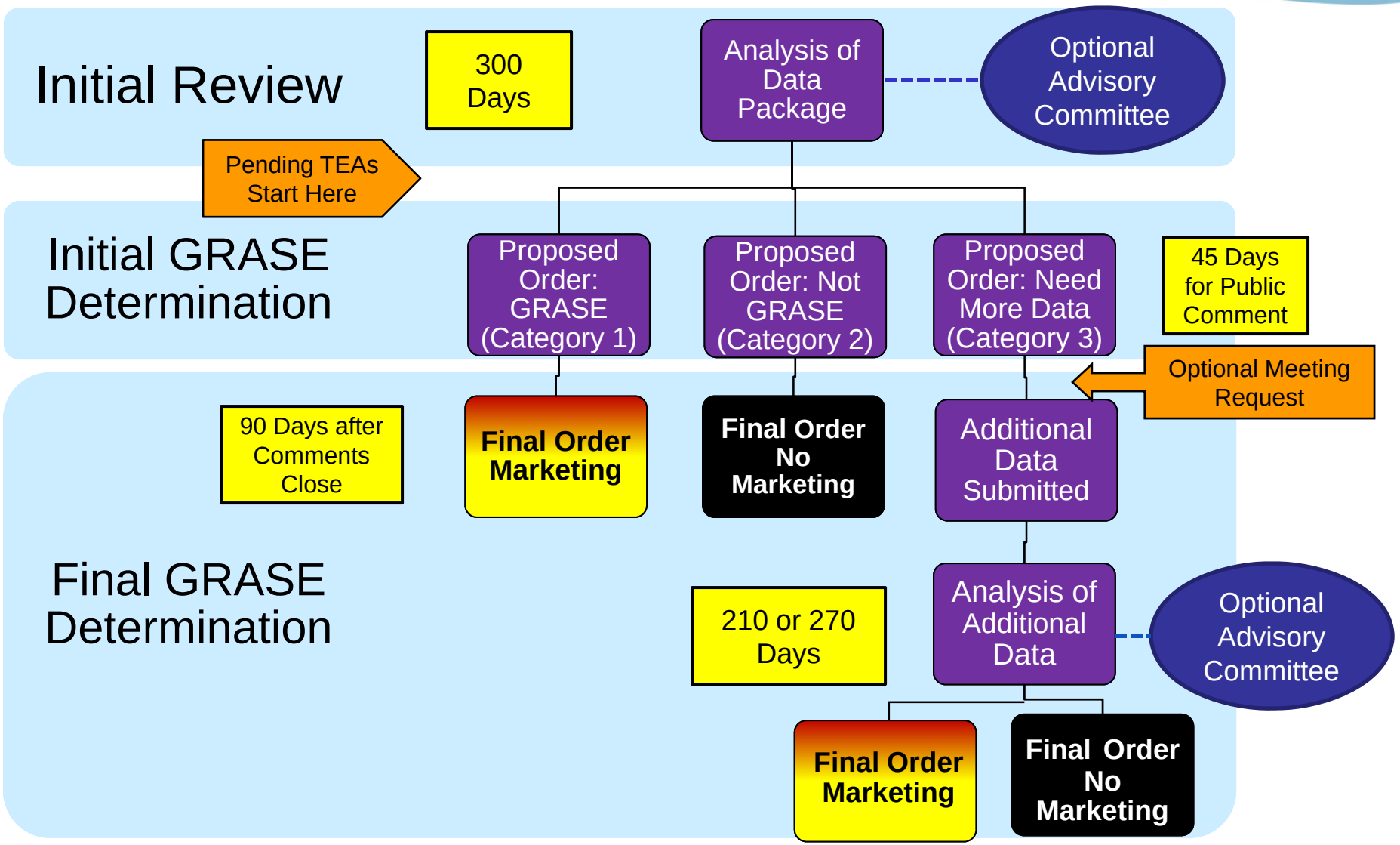
Sunscreen TEAs



Sunscreen TEAs (cont.)



What Happens After a Final Order?

- If ingredient is GRASE, marketing may occur under the terms of the final order
- If not GRASE, ingredient is non-monograph and requires an approved NDA for marketing unless GRASE determination is changed in the future

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Industry Obligations Under SIA: Sunscreens

- Submit applications sufficiently complete for review and filing within 60 days of submission
- If seeking a meeting with FDA after a Proposed Order, must request within 30 days
- Submit necessary data for Category 3 Proposed Order to allow FDA to reach a GRASE determination
- Information supporting a GRASE determination must be publically available

Industry Obligations Under SIA: Nonsunscreens

- Pending nonsunscreen TEAs may request a framework for review within 180 days of enactment [May 26, 2015]
  - Depending on framework, application may need to be sufficiently complete for review
- Information supporting a GRASE determination must be publically available

Recommendations for Meeting Requests

- Submit meeting requests to the ingredient docket with a copy to the Division of Nonprescription Drug Products
- Follow guidelines for formal meetings
  Guidance for Industry: Formal Meetings Between FDA and Sponsors or Applicants http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf
- Sunscreen meetings after proposed orders scheduled within 45 days of request
- Other meetings granted as Division resources allow
- Meetings are public; logistics will be posted to the docket
- FDA minutes will be posted to the docket

Recommendations for Framework Requests

(Pending non-sunscreen TEAs)

- Submit framework requests to the ingredient docket with a copy to the Division of Nonprescription Drug Products
- Clearly identify ingredient, sponsor contact information, docket number, and which of the four frameworks is requested

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SIA and Monograph Reform

- Scope of SIA is limited – overall monograph reform still needed
  - Finalizing tentative final monographs (TFMs)
  - Addressing safety changes
- Some aspects of SIA may be helpful for monograph reform
  - Format and content of data packages
  - Administrative order process
- FDA is committed to moving forward with reform and continuing dialogue with stakeholders
- Progress may be delayed due to resource constraints and demands of SIA and antiseptics consent decree

Summary and Next Steps

- Timelines to get new sunscreen ingredients on the market could be dependent on industry timelines for data submission
- Requirements under SIA are a very heavy lift for FDA with no additional resources
  - Other monograph work significantly impacted, including finalization of TFMs
- Overall monograph reform still needed
- Cooperative effort with industry and other stakeholders needed

Contact Information

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