



# The Looming Premarket Submission Deadline for Deemed Tobacco Products: The Road Ahead

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*Moderated by* **Stacy L. Ehrlich**, Partner, Kleinfeld, Kaplan & Becker, LLP and  
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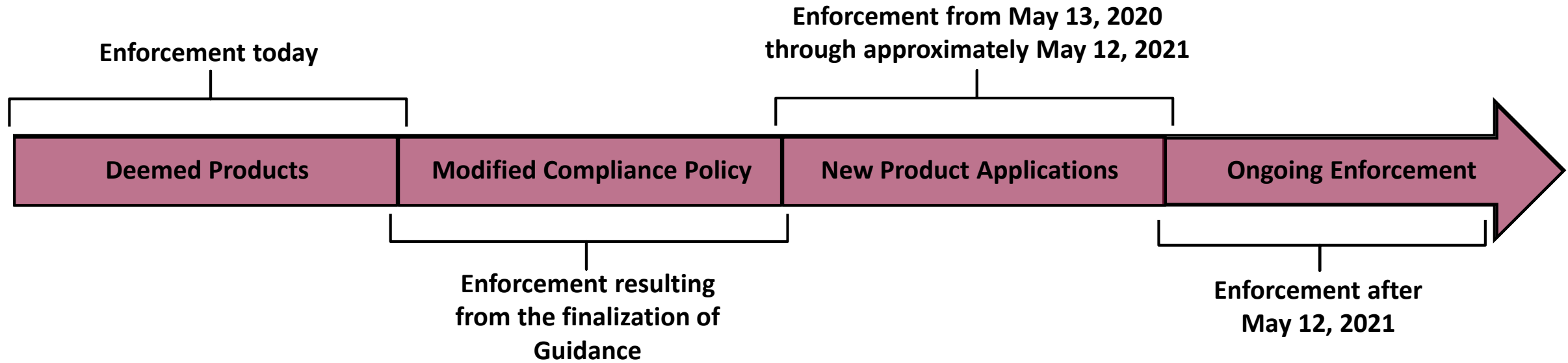


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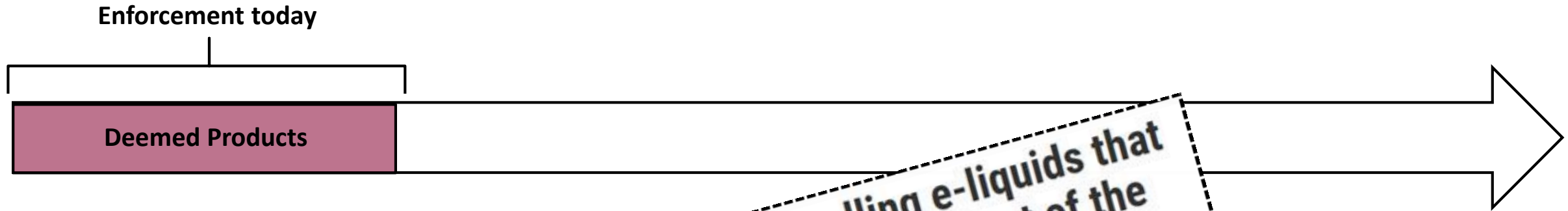
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# Enforcement Phases



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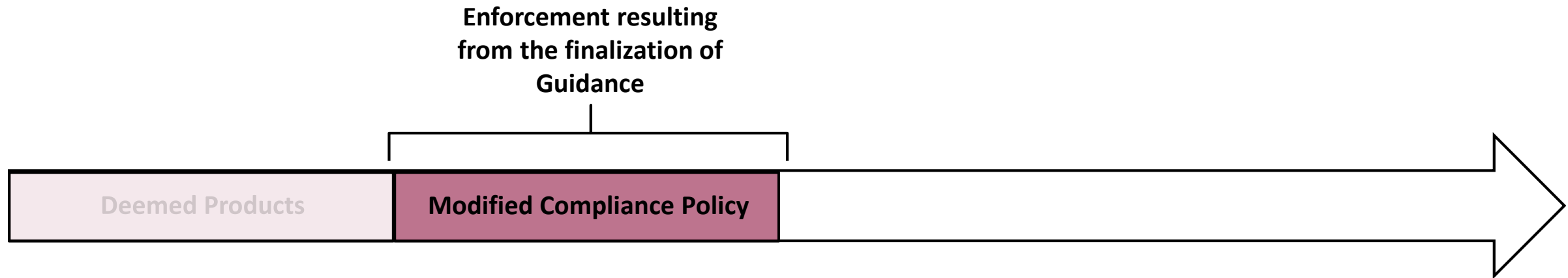


## Enforcement Considerations:

- Products on the market
- Use of enforcement

**FDA warns company for selling e-liquids that resemble kid-friendly foods as part of the agency's ongoing Youth Tobacco Prevention Plan**

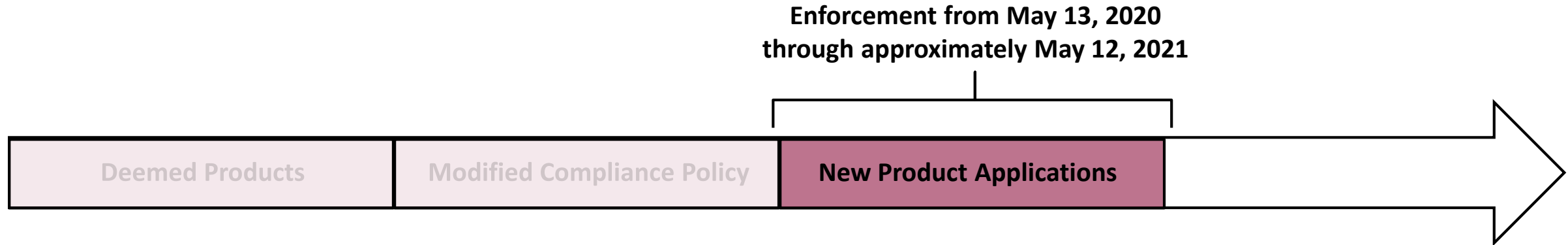
# Enforcement Phases



## Enforcement Considerations:

- Enforcement for certain products with characterizing flavors – scope not certain
  - March 2019 Draft Guidance
  - September 2019 Trump administration announcement

# Enforcement Phases



## Enforcement Considerations:

- Enforcement based on PMTA/SE submission status
  - No submission by 5/12/20
  - Refuse to Accept
  - Refuse to File
  - No Marketing Order
  - One-year review period
- Volume of applications and non-applying products

# Enforcement Phases

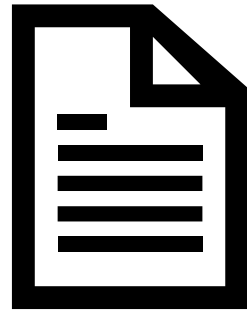


## Enforcement Considerations:

- New emerging products and/or retailers that are not on any enforcement radar
- Counterfeit
- Product standards

# Key Questions/Solutions

## Information



- PMTA Confidentiality
- Stakeholders – E.g. Trade, Consumers, States, Industry

## Resources



- FDA Enforcement Tools
- Resources Commensurate with Volume





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