

# Pediatric Research Equity Act (PREA)



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# Disclosure Statement

- I have no financial relationships to disclose relating to this presentation
- The views expressed in this talk represent my opinions and do not necessarily represent the views of FDA

# Outline



## Pediatric Research Equity Act (PREA)

### General Principles

- Description of the Statute
- Study Requirements
- Basis for Waivers and Deferrals



## Impact on Non-Prescription Products

### Unique study requirements

- Determination of safe use

# Pediatric Drug Development - General Principles

[ICH E11 \(R1\) Guideline](#)



- Ideally, products should have a pediatric assessment at the same time as adults when appropriate
- Promote early planning by drug developers regarding investigational product development in all pediatric age groups
- Ensures products anticipated to have public health benefits in the pediatric population are studied in all relevant age groups
- Applies to both new drug applications (NDAs) and biologics license applications (BLA)
- PREA does not apply to monograph active ingredients

# When PREA Requirements Apply

- Pediatric study requirements under PREA apply whenever the product being developed contains any of the features:
  - New active ingredient
  - New indication
  - New dosage form
  - New dosing regimen
  - New route of administration
  - Molecularly targeted cancer drugs



# Criteria for PREA Waivers

- Sponsors may request full (all pediatric ages) or partial (subset of pediatric population) waiver of required assessments:
  1. Necessary studies are impossible or highly impracticable; OR
  2. Evidence strongly suggests the drug/biologic would be ineffective or unsafe; OR
  3. Drug/biologic does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients AND is not likely to be used by a substantial number of pediatric patients; OR
  4. Reasonable attempts to produce a pediatric formulation necessary for that age group have failed (partial waiver only)



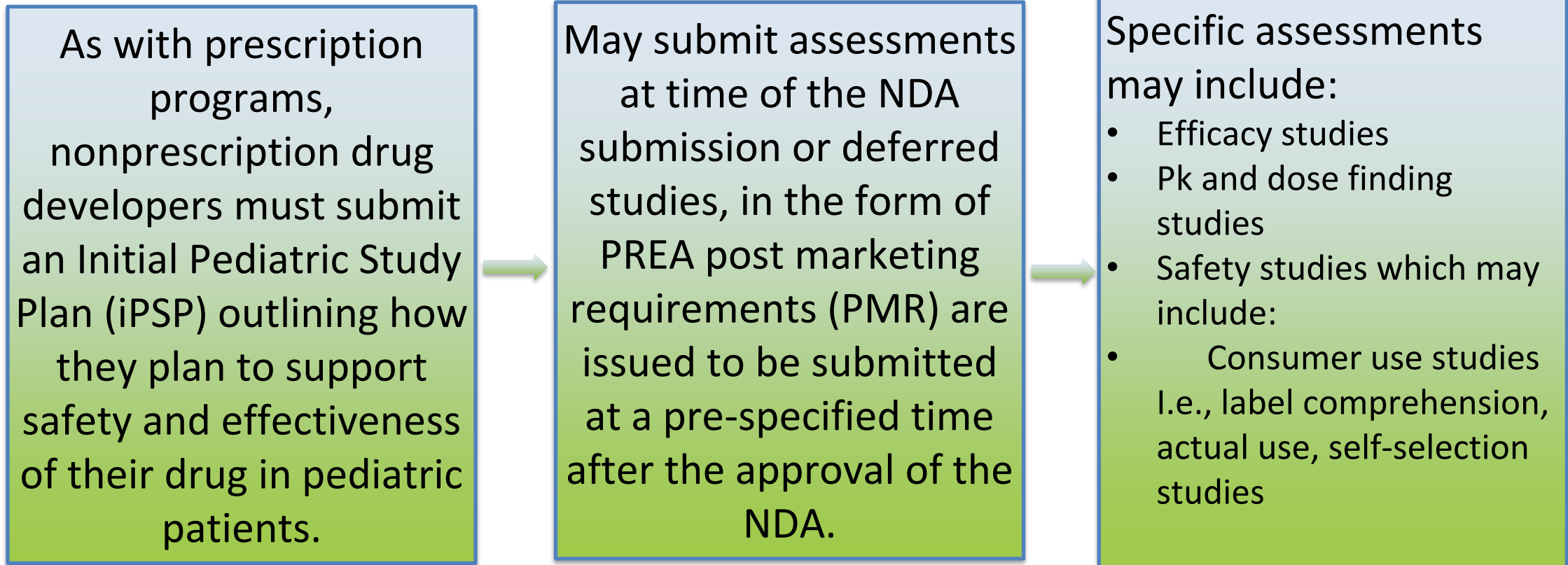
# Applying PREA to Non-Prescription Analgesic/Antipyretic Drug Development

FDA has authority to require studies in the pediatric population for new analgesic/antipyretic products developed in adults for OTC use that are subject to PREA

FDA must determine, if any of the waiver criteria would apply to a new product developed for adult use

- By determining if the new analgesic product would be unsafe or ineffective in the pediatric population or a subset of the population
- If it would be feasible to study the product in the pediatric population or a subset of the population
- If the product would provide a meaningful therapeutic benefit over existing therapies AND be used by a substantial number of pediatric patients

# PREA Required Assessment





# Thank You





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