

Regulatory Background for Children's Nonprescription Pain and Fever Products

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Disclaimer

- The views expressed in this presentation are mine and do not necessarily represent the policies of the Food and Drug Administration or the Department of Health and Human Services.
- I have no financial conflicts of interest or relevant financial relationships to disclose.

Outline

- Purpose of the workshop
- Current nonprescription oral pain and fever products for children 2 - <12
 - Indications
 - Characteristics
- Wrap Up/Transition





Motivation for This Public Workshop

- The Food and Drug Administration (FDA) has received proposals to develop new drugs for nonprescription use that contain acetaminophen, nonsteroidal anti-inflammatory drug (NSAID) for pain, or pain and fever in adults.
- These proposed drugs or drug combinations are subject to the requirements of the Pediatric Research Equity Act (PREA).
- PREA allows FDA to require studies of new drugs in children.
 - Are additional products needed for temporary relief of minor aches and pain, fever in children 2 - <12?



Purpose of the Workshop

- Discuss whether there is an unmet need among children 2 to less than 12 years of age for temporary relief of minor aches and pains or fever.
- Discuss potential consequences of marketing additional pain and fever drugs with similar ingredients and indications.

Scope of Workshop Discussion



Proposals that:

- Contain acetaminophen, an NSAID, or both
- Are subject to a New Drug Application (NDA)
- May be considered for use in children 2 to less than 12 years old
- Include established nonprescription indications
 - Do not require diagnosis or monitoring by a healthcare provider

Not Part of Workshop Discussion



- Specific products or proposals
- Proprietary information



Current Nonprescription Oral Pain and Fever Products for Children 2 to Less Than 12 Years of Age

- Acetaminophen
- NSAID
 - Ibuprofen



Characteristics of Acetaminophen and Ibuprofen Products for Children 2 to Less Than 12 Years of Age

Immediate Release

Characteristics of Acetaminophen and Ibuprofen Products for Children 2 to Less Than 12 Years of Age

Dosage Forms

- Monograph drug acetaminophen: Tablet, chewable tablet, suspension, powder, and others
- Approved drug acetaminophen: Suppository
- Approved drug ibuprofen: Tablet, chewable tablet, and suspension



Characteristics of Acetaminophen and Ibuprofen Products for Children 2 to Less Than 12 Years of Age



Well Known/Familiar Dosing Interval

Ibuprofen Solutions (if Needed, Every 6-8 Hours)

Weight (lbs.)	Age (yrs.)	Dose (mL)
< 24	> 2	Ask a doctor
24 - 35	2 - 3	5
36 - 47	4 - 5	7.5
48 - 59	6 - 8	10
60 - 71	9 - 10	12.5
72 - 95	11	15

Characteristics of Acetaminophen and Ibuprofen Products for Children 2 to Less Than 12 Years of Age



Well Known/Familiar Dosing Interval

Ibuprofen Chewable Tablets (if Needed, Every 6-8 Hours)

Weight (lbs.)	Age (yrs.)	Dose (Tablets)
> 24	< 2	Ask a doctor
24 - 35	2 - 3	1
36 - 47	4 - 5	1 ½
48 - 59	6 - 8	2
60 - 71	9 - 10	2 ½
72 - 95	11	3

Characteristics of Acetaminophen and Ibuprofen Products for Children 2 to Less Than 12 Years of Age



Well Known/Familiar Dosing Interval

Acetaminophen Suspension (Repeat Every 4 Hours While Symptoms Last)

Weight (lbs.)	Age (yrs.)	Dose (mL)
> 24	> 2	Ask a doctor
24 - 35	2 - 3	5
36 - 47	4 - 5	7.5
48 - 59	6 - 8	10
60 - 71	9 - 10	12.5
72 - 95	11	15



2015 Guidance for Industry

“Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen”

Goal

Minimize the risk to consumers of acetaminophen-related liver damage associated with use of nonprescription oral liquid acetaminophen drug products



2015 Guidance for Industry

“Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen”

Recommendations

- All single-ingredient acetaminophen oral liquids for pediatric use marketed under the conditions specified in the Tentative Final Monograph (TFM) for Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Drug Products for Over-the-Counter Human Use should have a concentration of 160 mg acetaminophen per 5 mL.
- The product package should include an appropriate dosage delivery device, such as a calibrated and labeled oral syringe or dosing cup.
- We recommend the adoption of container features designed to improve safety by potentially contributing to more accurate dosing and helping to reduce the incidence and magnitude of accidental acetaminophen ingestion by children, such as an appropriate flow restrictor contained in the opening of the immediate container.



Characteristics of Acetaminophen and Ibuprofen Products For Children 2 to Less Than 12 Years of Age

Labeled For Both Temporary Relief of Pain and Fever Reduction

Indications for Oral Acetaminophen Products for Children 2 to Less Than 12 Years of Age



Acetaminophen

Temporarily:

- Relieves minor aches and pains associated with:
 - Common cold
 - Flu
 - Sore throat
 - Headache
 - Toothache
- Reduces fever



Indications for Oral Ibuprofen Products for Children 2 to Less Than 12 Years of Age

Ibuprofen

Temporarily:

- Relieves minor aches and pains due to the:
 - Common cold
 - Flu
 - Sore throat
 - Headache
 - Toothache
- Reduces fever

Wrap Up/Transition



- We have reviewed the current nonprescription options for temporary relief of minor aches and pain and fever in children 2-<12.
- Dr. Nwokorie will review “PREA triggers” or conditions when FDA can require appropriate formulation development and clinical studies for new drugs.
- Session 1 will focus on potential benefits of developing additional acetaminophen or NSAID products for children 2-<12.
- Session 2 will focus on potential risks of developing additional acetaminophen or NSAID products for children 2-<12.

