$FAQS \mid \underset{\text{dose (chewable) strength change}}{\text{pediatric acetaminophen solid}}$

1. Why is this change being made?

This transition is consistent with a 2011 FDA Advisory Committee recommendation that the FDA consider a single strength for solid pediatric acetaminophen products. The decision to only offer the 160mg strength was based upon a number of factors: 1) the 160 mg is currently the most widely used solid oral dosage strength; 2) this dosage strength aligns with the most common single ingredient pediatric liquid acetaminophen medicine concentration (160mg/5mL); and 3) the need to take fewer tablets per dose is likely to improve dosing compliance, especially for older children, who are more likely to use the solid dosage forms.

2. Is it still safe for my patients to use the 80mg product?

The pediatric acetaminophen products currently on the market can continue to be used as labeled. Please remind your parents/caregivers to always read and follow the entire Drug Facts label.

3. Are all manufacturers and retailers making this change?

Each individual manufacturer and retailer ultimately has to decide on its own on whether to make the change to manufacture only the 160mg strength pediatric acetaminophen product. This change has support from a broad range of stakeholders.

4. When will all of the manufacturers and retailers transition?

Each individual manufacturer and retailer ultimately has to decide on its own on whether to make the change to manufacture or sell only the 160mg strength pediatric acetaminophen product.

5. How do I recommend dosing if I don't know what product the caregiver/parent has or will purchase?

Please always verify the acetaminophen dosage strength (80mg or 160mg) a parent is using before providing dosing directions. Always remind caregivers/parents to read and follow the Drug Facts label dosing directions of the specific medication that they are using. Please also remind them to always keep the medicine in its original container as it contains the full labeling instructions and strength for the product.