December 8, 2014

Alice Tu, MD
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Dr. Tu:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 62,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, I am pleased to provide comments on the Over-the-Counter Pediatric Liquid Drug Products Containing Acetaminophen: Draft Guidance for Industry.

The AAP applauds that the draft guidance adopts a uniform concentration for single-ingredient acetaminophen oral liquids. In the face of ample evidence demonstrating that multiple concentrations confuse parents and result in inappropriate dosing leading to injury in children, there is no reason not to have a single concentration for over-the-counter (OTC) pediatric liquid medicines. However, we are concerned that the draft guidance continues to recognize combination OTC liquid oral drug products that contain acetaminophen. In its testimony to the Food and Drug Administration (FDA)’s Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the Pediatric Advisory Committee (PAC), the AAP called for all OTC drug products, including acetaminophen, to be single ingredient in order to maximize patient safety. Parents are often unaware that drug products, including prescription products, may also contain acetaminophen. As such, the AAP feels strongly that there is no reason why OTC combination products containing acetaminophen should be on the market for children.

While the adoption of metric dosing recommendations is important, the AAP is dismayed that the draft guidance is not explicit in calling for weight-based dosing with specific guidance on labeling for all children ages 6 months through 12 years. The draft guidance recommends that principal display panels (PDPs) clearly indicate the age range and units of age (e.g. months or years). This standard is insufficient and too broad. Weight should replace age for dosing purposes as it constitutes a more accurate basis for determining optimal dosing for an individual child than age alone. The absence of specific instructions for use of these products in children from ages 6 months to 2 years does little to address the large number of adverse events that are associated with this age group.
The draft guidance provides helpful recommendations on dosage delivery devices that should set a floor, not a ceiling on standards for industry compliance with these devices. The AAP would reiterate that there should be consistency among all dosing devices and that all liquid OTC products contain flow limiting capacity. In no circumstance should a dosage delivery device use teaspoon or tablespoon measures. The AAP hopes that there will be active enforcement of compliance with the recommendations on dosing devices in the draft guidance by the FDA.

The AAP remains deeply troubled that the FDA still has taken no new regulatory action to address pediatric OTC cough and cold medicines. It is now more than seven years since the FDA’s Joint Meeting of the NDAC and PAC where those committees agreed with the AAP recommendation that, in the face of evidence of no effectiveness and certain evidence of harm, OTC cough and cold medicines be relabeled as follows:

*This product has been shown to be ineffective in the treatment of cough and cold in children under six years of age. Serious adverse reaction, including by not limited to death have been reported with the use, misuse, and abuse of this product.*

Still today, efficacy of these cough and cold products for children, including those that contain acetaminophen, has not been proven. As such, the AAP continues to recommend that OTC cough and cold products be labeled against their use in children under six years of age. The AAP renews its call on the FDA to publish the revised monograph for pediatric OTC cough and cold products without delay.

Thank you for your consideration of our comments. If we can provide further assistance, please contact Tamar Magarik Haro in our Washington Office at (202) 347-8600.

Sincerely,

/s/

James M. Perrin, MD, FAAP
President

JMP/tmh