



October 16, 2019

Honorable Nita Lowey  
House Committee on Appropriations  
2365 Rayburn House Office Building  
Washington, DC 20515

Honorable Kay Granger  
Committee on Appropriations  
1026 Longworth House Office Building  
Washington, DC 20515

Honorable Sanford Bishop  
House Appropriations Subcommittee on Agriculture,  
Rural Development and Food and Drug Administration  
2407 Rayburn HOB  
Washington, DC 20515

Honorable Jeff Fortenberry  
House Appropriations Subcommittee on Agriculture,  
Rural Development and Food and Drug Administration  
1514 Longworth HOB  
Washington, DC 20515

Dear Chairs Lowey and Bishop and Ranking Members Granger and Fortenberry:

I write on behalf of Safe Kids Worldwide, a grass roots network of more than 420 coalitions across the nation with the mission of preventing unintentional injury among kids 19 and under. Such injuries are the number one killer of children in that age group in the United States. Medication dosing errors are among the preventable injuries on which we work to reduce. Thus, the need for complete and clear labeling and age recommendations for the youngest set of pain sufferers is critical. We appreciate that the Committee made a strong statement and set an aggressive timetable for the Food and Drug Administration (FDA) to allow weight-based dosing information on acetaminophen products for children six months to two years of age.

This has been an issue for far too long, dating back to the last century. In 2011, an FDA expert panel voted unanimously in favor of allowing this acetaminophen labeling instruction, as did an FDA advisory panel 15 years before that. In April 2012, Safe Kids wrote to the FDA Commissioner requesting the agency to take this action. To this day, the label on non-prescription acetaminophen tells parents and caregivers of children 6 to 23 months to "consult a doctor" or "ask a doctor." Safe Kids coalition leaders have a unique understanding of the concerns a parent faces every day. It is impractical and risky to add on this challenge of needing to contact a doctor for dosing instructions as a child is crying in pain. Paradoxically, manufacturers of non-prescription ibuprofen have been able to state specific dosing instructions for children 6 months to 23 months for more than 15 years.

We support the Committee's instruction to the agency to provide an aggressive timetable and plan for updating the monograph to allow weight-based instructions on acetaminophen products for kids 6 to 23 months. By copy of this letter to Acting FDA Commissioner Norman Sharpless, we urge the agency to take action on this matter. Thank you for your leadership.

Sincerely,

A handwritten signature in blue ink, appearing to read "A Green".

Anthony Green  
Chief Advocacy and Network Officer