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Drug Safety Communication: New Age Limit for Opioid Cough and Cold Medicines

Prescription cough and cold medicines containing codeine or hydrocodone are available in combination with other medicines, such as antihistamines and decongestants, in prescription medicines to treat coughs and symptoms associated with allergies or the common cold. These medications may carry serious risks, including slowed or difficult breathing, misuse, abuse, addiction, overdose, and death, all of which appear to be a greater risk among children and adolescents younger than 18 years of age.

On January 11, 2018, the U.S. Food and Drug Administration (FDA) announced they are requiring safety labeling changes for prescription cough and cold medicines containing codeine or hydrocodone to limit the use of these products to adults 18 years of age and older because the risks of these medicines outweigh their benefits in children younger than 18 years of age. The FDA is also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the *Boxed Warning* on drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

Health care professionals should be aware that the FDA is changing the age range for which prescription opioid cough and cold medicines are indicated. These products will no longer be indicated for use in children, and their use in this age group is not recommended. Health care professionals should reassure parents that cough due to a cold or upper respiratory infection is self-limited and generally does not need to be treated. For those children in whom cough treatment is necessary, alternative medicines are available. These include over-the-counter (OTC) products such as dextromethorphan, as well as prescription benzonatate products.

To read the full MedWatch safety alert, which includes a list of the prescription cough and cold drugs affected, refer to the "FDA Drug Safety Communication: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older" article found on the [Drug Safety and Availability](#) web page of the FDA website.