FDA News Release

FDA warns against the use of homeopathic teething tablets and gels

For Immediate Release

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Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm523642.htm)

The U.S. Food and Drug Administration is warning consumers that homeopathic teething tablets and gels may pose a risk to infants and children. The FDA recommends that consumers stop using these products and dispose of any in their possession.

Homeopathic teething tablets and gels are distributed by CVS, Hyland's, and possibly others, and are sold in retail stores and online.

Consumers should seek medical care immediately if their child experiences seizures, difficulty breathing, lethargy, excessive sleepiness, muscle weakness, skin flushing, constipation, difficulty urinating, or agitation after using homeopathic teething tablets or gels.

"Teething can be managed without prescription or over-the-counter remedies," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "We recommend parents and caregivers not give homeopathic teething tablets and gels to children and seek advice from their health care professional for safe alternatives."

The FDA is analyzing adverse events reported to the agency regarding homeopathic teething tablets and gels, including seizures in infants and children who were given these products, since a **2010 safety alert (/NewsEvents/Newsroom/PressAnnouncements/ucm230761.htm)** about homeopathic teething tablets. The FDA is currently investigating this issue, including testing product samples. The agency will continue to communicate with the public as more information is available.

Homeopathic teething tablets and gels have not been evaluated or approved by the FDA for safety or efficacy. The agency is also not aware of any proven health benefit of the products, which are labeled to relieve teething symptoms in children.

The FDA encourages health care professionals and consumers to report adverse events or quality problems experienced with the use of homeopathic teething tablets or gels to the <u>FDA's MedWatch Adverse Event Reporting program (http://www.f-da.gov/Safety/MedWatch/default.htm)</u>:

- Complete and submit the report online at <u>www.fda.gov/medwatch/report.htm</u> (<u>http://www.fda.gov/MedWatch/report.htm</u>); or
- Download and complete the <u>form (/downloads/AboutFDA/ReportsManuals-Forms/Forms/UCM349464.pdf)</u>, then submit it via fax at 1-800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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