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FDA warns teething products with benzocaine may pose safety risk

The Food and Drug Administration (FDA) has issued another warning about teething products containing benzocaine and is asking companies to stop selling them.

"Because of the lack of efficacy for teething and the serious safety concerns we've seen with over-the-counter benzocaine oral health products, the FDA is taking steps to stop use of these products in young children and raise awareness of the risks associated with other uses of benzocaine oral health products," FDA Commissioner Scott Gottlieb, M.D., said in a news release.

Benzocaine is sold under brands like Anbesol, Baby Orajel, Cepacol, Chloraseptic, Hurricaine, Orabase, Orajel and Topex along with generic and store brands advertised as relieving oral pain, according to the FDA.

However, benzocaine has been linked to methemoglobinemia, which causes a reduction in blood oxygen and can be fatal. There have been about 400 cases of benzocaine-related methemoglobinemia, including 119 cases between February 2009 and October 2017, according to the FDA, which has issued several warnings over the years.

The FDA is asking companies to stop selling teething products with benzocaine and said it will initiate regulatory action if necessary. All other oral health products with benzocaine will have a contraindication for children under 2 years and for teething relief. These over-the-counter products as well as prescription local anesthetics also will add warnings about methemoglobinemia to their labels.

The Academy recommends avoiding teething products with benzocaine as well as the plant poison belladonna. Instead, it suggests parents use their fingers to massage a child's gums. Children can use teething rings made of firm rubber but should avoid rings that are frozen.

Consumers who have used benzocaine products should seek immediate medical attention if they experience symptoms such as pale, gray or blue skin, lips or nail beds; shortness of breath, fatigue; headache; lightheadedness and rapid heart rate. They also should report adverse reactions to the FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report.