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FDA clamps on OTC benzocaine teething products

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The agency announced that OTC oral health products containing the pain reliever benzocaine for the temporary relief of sore gums due to teething in infants or children should no longer be marketed and is asking companies to stop selling these products for such use.

Singapore- The U.S. Food and Drug Administration is warning consumers that over-the-counter (OTC) teething products containing benzocaine pose a serious risk to infants and children. The agency announced that OTC oral health products containing the pain reliever benzocaine for the temporary relief of sore gums due to teething in infants or children should no longer be marketed and is asking companies to stop selling these products for such use. If companies do not comply, the FDA will initiate a regulatory action to remove these products from the market. Also, the agency is requesting that companies add new warnings to all other benzocaine oral health products to describe certain serious risks.

"The FDA is committed to protecting the American public from products that pose serious safety risks, especially those with no demonstrated benefit," said FDA Commissioner Scott Gottlieb, M.D. "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. In addition to our letters to companies who make these products, we urge parents, caregivers and retailers who sell them to heed our warnings and not use over-the-counter products containing benzocaine for teething pain. We will also continue working with Congress to modernize our over-the-counter drug monograph regulatory framework as part of our mission to protect and promote public health."

Benzocaine is marketed to help relieve pain from a variety of conditions such as teething, sore throat, canker sores and irritation of the mouth and gums. The products are sold as gels, sprays, ointments, solutions and lozenges under the OTC brand names Anbesol, Baby Orajel, Cepacol, Chloraseptic, Hurricaine, Orabase, Orajel and Topex, as well as store brands and generics. In a Drug Safety Communication issued, the agency builds on its previous warnings about risks associated with benzocaine products for methemoglobinemia. This dangerous condition is the result of elevated levels of methemoglobin in the blood and it can lead to death. It causes the amount of oxygen carried through the blood to be greatly reduced. The FDA also outlined these safety concerns in letters that the agency sent to manufacturers of these products. The agency made

specific recommendations to manufacturers in order to protect patients and make sure the most up-to-date drug safety information will appear on drug labels.

The FDA is requiring manufacturers of all FDA-approved prescription local anesthetics to standardize warning information about the risk of methemoglobinemia in product labeling across this class of products. Manufacturers of approved, prescription local anesthetics will have 30 days to reply to the FDA's letter regarding these new Safety Labeling Changes.