



Safetec of America, Inc.
887 Kensington Avenue
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05/29/18

Subject: Regulatory Announcement - OTC oral drug products

On May 23, 2018, the FDA issued a safety alert warning that over-the-counter (OTC) oral drug products containing benzocaine should not be used to treat infants and children younger than 2 years. FDA announced that these products carry serious risks and provide little to no benefits for treating oral pain, including sore gums in infants due to teething. Benzocaine, a local anesthetic, can cause a condition in which the amount of oxygen carried through the blood is greatly reduced. This condition, called methemoglobinemia, can be life-threatening and result in death.

Safetec of America manufactures an OTC oral pain relief for adults and children 2 years or older.

Safetec of America does not manufacture or market any oral pain products for teething or for children under the age of 2 years.

Presently, Safetec's label for the oral pain relief product specifically states the product is for adults and children ages 2 years or older. The FDA is however urging manufacturers of OTC oral drug products containing benzocaine for adults and children 2 years and older to add more warnings to labels.

Effective on or before 01/01/19, Safetec of America will implement the following additional verbiage on all labels for OTC oral drug products containing benzocaine:

- Adding a warning about methemoglobinemia;
- Adding contraindications, FDA's strongest warnings, directing parents and caregivers not to use the product for teething and not to use in infants and children younger than 2 years; and
- Revising the directions to instruct parents and caregivers not to use the product in infants and children younger than 2 years.

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