DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993-0002

May 12, 2014

Jay E. Sirois, Ph.D.
Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006

Dear Dr. Sirois:

This letter is in response to your October 12, 2012, request for FDA to exercise enforcement discretion regarding the addition of a methemoglobinemia warning to Drug Facts labeling for over-the-counter (OTC) benzocaine liquid and gel topical products indicated for relieving oral discomfort.

As you are aware, benzocaine OTC drug products intended to relieve oral discomfort are being evaluated for conditions of general recognition of safety and effectiveness as oral anesthetic/analgesic products under the Tentative Final Monograph (TFM) for OTC Oral Health Care Drug Products (56 FR 48302, September 24, 1991). The proposed labeling under this TFM does not presently include a methemoglobinemia warning.

Nonetheless, FDA has expressed concerns about the risk of methemoglobinemia associated with OTC oral health care benzocaine drug products.[1] To this end, we reviewed your proposal to include a warning under Drug Facts that the use of OTC oral health care benzocaine drug products is associated with the rare, but serious condition, methemoglobinemia. Although we do not accept your proposal, we have concluded that the alternative language discussed below represents a more appropriate warning. Thus, we intend to exercise enforcement discretion for CHPA members and any other manufacturer or marketer of OTC oral health care benzocaine liquid, spray, lozenge, and gel topical drug products that includes a methemoglobinemia warning in the Drug Facts as follows:

> **"METHEMOGLOBINEMIA WARNING"** (these two words in bold print and capital letters as the first statement under the heading "WARNINGS"): Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if you or a child in your care develops:

[1] *See* FDA Safety Alert - Benzocaine Topical Products: Sprays, Gels and Liquids - Risk of Methemoglobinemia (available at: http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm250264.htm)

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Should FDA issue any document, including any regulation, guidance, or other statement that supersedes or withdraws this expression of intent to exercise enforcement discretion, we expect manufacturers and labelers to revise their labeling accordingly.

We appreciate CHPA and its members continued efforts to ensure the safe use of OTC drug products. Please contact Sudha Shukla at Sudha.Shukla@fda.hhs.gov, or 301-796-3345 if you have further questions.

Sincerely,

Thomas J. Cosgrove, J. D.
Director
Office of Unapproved Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research