DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Michael A. Carome, M.D., et al.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Re: Docket No. FDA-2014-P-1256

Dear Dr. Carome:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated July 28, 2014, submitted to Docket No. FDA-2014-P-1256 in the Division of Dockets Management. Your petition requests that the FDA immediately take the following actions with respect to over-the-counter (OTC) benzocaine products:

(1) Reopen the administrative record for the monograph for OTC oral health care drug products,

(2) Revise the proposed required labeling for OTC benzocaine oral health care drug products to remove the infant teething indication and include a contraindication advising against using gel and liquid benzocaine products for teething pain, and

(3) Require a warning label regarding methemoglobinemia for all remaining OTC benzocaine products covered by the monograph.

FDA has been unable to reach a decision on your petition because it raises significant/complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions regarding this matter, please refer to the docket number above, and submit all inquiries to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Maryland 20852.

Sincerely,

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research