



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 23 2011

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your November 15, 2011 letter, cosigned by 12 of your colleagues, regarding the continued availability of over-the-counter (OTC) inhalers for the treatment of asthma. Your letter requests that the Environmental Protection Agency (EPA) exercise its enforcement discretion to allow for continued distribution of existing inventories of the over-the-counter (OTC) inhaler Primatene Mist beyond the December 31, 2011, date set by the Food and Drug Administration's (FDA's) 2008 rulemaking.

On November 22, 2011, we received a similar request from the National Association of Chain Drug Stores (NACDS). We responded to NACDS to share some context for how such requests are considered by the EPA in other settings, and to summarize information about the December 31 transition that has been made public by various stakeholders, including the American Lung Association and the American College of Allergy, Asthma and Immunology. We enclose for your information our letter to NACDS.

Again, thank you for your letter. If you have further questions, please contact me or your staff may call Diann Frantz in the EPA's Office of Congressional and Intergovernmental Relations at (202) 564-3668.

Sincerely,

A handwritten signature in black ink, appearing to read "Arvin Ganesan".

Arvin Ganesan
Associate Administrator

Enclosure