



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

1395 '00 FEB 28 A9:42

FEB 24 2000

The Honorable Edolphus "Ed" Towns  
House of Representatives  
Washington, D.C. 20515-3210

Dear Mr. Towns:

Thank you for your letter of November 9, 1999, regarding the Food and Drug Administration's (FDA) Notice of Proposed Rulemaking on the use of Ozone-Depleting Substances (ODS).

Your letter expressed concern that "under the NPRM framework, a new CFC-containing MDI device may still be deemed essential even though that device offers no new health benefits." Your letter has been forwarded to Docket No. 97N-0023 for inclusion in the record of comment on the proposed rule. FDA will further review this issue during consideration of comments to the docket, and your comments will be addressed at such time as FDA publishes a final rule on this matter.

Please be assured that FDA remains committed to exercising its responsibilities under the Montreal Protocol and Clean Air Act in a way that will facilitate the transition to non-CFC based metered dose inhalers while protecting the health of patients who depend on those products.

Sincerely,

*Phil Broadbent for*

Melinda K. Plaisier  
Associate Commissioner  
for Legislation

97N-0023

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**EDOLPHUS "ED" TOWNS**

MEMBER OF CONGRESS  
10TH DISTRICT, NEW YORK

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FINANCE AND HAZARDOUS  
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**Congress of the United States**

**House of Representatives**

Washington, DC 20515-3210 A9:42

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November 9, 1999

Jane E. Henney, M.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner Henney:

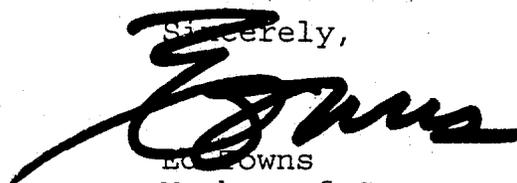
As you know, FDA recently published a Notice of Proposed Rulemaking (NPRM) regarding the use of Ozone-Depleting Substances; Essential Use Determination, 64 Federal Register 47719 (September 1, 1999). As the FDA itself suggested in the introductory section, the NPRM proposes a national transition framework away for CFC-containing Metered Dose Inhalers (MDIs) which balances the needs and concerns of asthmatics and the ozone-depletion health and environmental goals of the Clean Air Amendments of 1990, which implemented the Montreal Protocol. For that the FDA is to be commended. However, there is at least one area in the NPRM that the FDA should consider clarifying.

It is my understanding that under the NPRM framework, a new CFC-containing MDI device may still be deemed essential even though that device offers to no new health benefits. It makes little sense to expand the universe of patients dependent on CFC-MDIs at the very time that the FDA is attempting to effect a smooth transition to CFC-free devices. I support a clarification of the proposed rule to ensure that the FDA will approve new CFC MDIs only if it determines that such devices offer a new important health benefit. I understand that the major patient, physician, health, environmental and industry groups which have followed this issue have expressed their written support for his clarification. This will have no impact on the NPRM's framework for transition of currently used and marketed MDIs.

No. 99-7122

Thank you for your consideration and attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Ed Towns". The signature is stylized with a large, sweeping initial "E" and a long, horizontal flourish extending to the right.

Ed Towns  
Member of Congress