Congress of the United States

Washington, DC 20515

June 30, 2000

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

Dear Commissioner Henney:

As you know, on September 1, 1999, in accordance with the Montreal Protocol and the Clean Air Act Amendments of 1990 (CAA), FDA published a Notice of Proposed Rulemaking (NPRM) setting forth its proposed policy for phasing out metered-dose inhalers (MDIs) containing chlorofluorocarbons (CFCs) used for the treatment of asthma and other respiratory diseases (64 Federal Register 47719). The NPRM is improved from the framework FDA proposed in its March 1997 Advanced Notice of Proposed Rulemaking. In particular, we are pleased that FDA has eliminated the therapeutic class phase-out approach that raised concerns for physicians and patients. However, we believe that there is still at least one area of the transition which does not adequately protect the interests of patients while balancing environmental concerns.

Under the NPRM framework, a new CFC-containing MDI made with a currently marketed drug substance will be automatically deemed essential by FDA, even if that product offers no new important health benefit. This could result in patients being switched to a new CFC inhaler for only a short period of time, or it could create unintended market disincentives toward a smooth transition which places the concerns of patients first. It is also inconsistent with the NPRM's approach toward new chemical entities in devices containing CFCs; any such product would only be deemed essential if, after a thorough review, FDA finds that the product would provide "unavailable important public health benefits."

Section 601(8)(B) of the Clean Air Act gives FDA ample authority to subject new CFC MDI products with existing active ingredients to the same essentiality review as CFC MDIs with new chemical entities. FDA also has authority under CAA section 604(d)(2) to determine that CFC production for new CFC MDI products would be inconsistent with the Montreal Protocol and/or not "necessary."

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We are also aware of the support expressed by major respiratory physician and patient groups for proposed Decision XI/15 at the 11th Meeting of the Parties of the Montreal Protocol in Beijing in December of last year (See attached letter dated September 21, 1999). That Decision included a provision regarding the essentiality of newly-approved CFC MDIs which allowed for essential use status for products approved prior to the 11th Meeting and for products approved after that date which the national authority determined would serve an otherwise unmet medical need. As we have indicated above, FDA has the authority under the Clean Air Act to make such a determination for any newly-approved product. We are therefore disappointed that the U.S. delegation to the Beijing Meeting took an unyielding position in opposition to this provision of Decision XI/15 and did not seek, instead, to craft acceptable language. This opposition contributed to the Decision not being adopted. The Meeting's failure to reach consensus on Decision XI/15 was a setback for patients and the environment.

We therefore urge FDA to fulfill its responsibilities under the CAA by including in the Final Rule a requirement for case-by-case review of the essentiality of, and the necessity of CFC production for, new CFC MDI products – regardless of whether such products contain an existing or new active ingredient. After several years of division and debate concerning the MDI transition, it appears that most parties agree upon the goal of eliminating the use of ozone-depleting substances in MDIs while protecting patient health. Inclusion of the above provision in the Final Rule, and support for a corresponding provision in a Protocol decision this year, will send a clear signal that the U.S. government is fully committed to this goal and help to level the playing field for the United States in the global economy.

Thank you for your consideration and attention to this matter.

Sincerely,

John D. Dingell, M.C.

Michael Bilirakis, M.C.

Steny H. Hoyer, M.C. Richard Burr, M.C.

Patrick J. Kennedy, M.C.

cc: Madeleine K. Albright, Secretary of State
Carol M. Browner, EPA Administrator