DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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The Honorable Christopher H. Smith
House of Representatives
Washington, D.C. 20515-3004

Dear Mr. Smith:

Thank you for your letter of November 5, 1999, co-signed by six of your colleagues, regarding the Food and Drug Administration's (FDA) Notice of Proposed Rulemaking on the use of ozone-depleting substances (ODS). We appreciate having the benefit of your views.

Your letter expressed concern that "under certain circumstances, new CFC-based MDIs may be approved by FDA although such devices may not offer new health benefits to patients or any improvement in MDIs utilized by patients." Your letter has been forwarded to Docket No. 97N-0023 for inclusion in the record of comment on the proposed rule. As you requested, 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. A similar letter has been sent to your co-signers.

Sincerely,

Marilyn Dugast for
Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
(No. 97N-0023)

97N-0023

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Congress of the United States

Washington, DC 20515

November 5, 1999

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

Dear Commissioner Henney:

As you know, the FDA recently published a Notice of Proposed Rulemaking (NPRM) regarding the use of Ozone-Depleting Substances; Essential Use Determinations, 64 Fed. Reg. 47719 (September 1, 1999).

The NPRM proposes a national transition strategy for CFC-based metered-dose-inhalers (MDIs) and attempts to balance the needs and concerns of patients, including asthmatics and those who experience other lung disorders, with the obligations embodied in the Montreal Protocol to take appropriate measures to protect human health and the environment while taking into account technical and economic considerations. To this end, the NPRM proposes several criteria under which it will determine whether an essential use designation should be maintained for a CFC-based MDI, or whether it should be removed.

We believe that the NPRM represents several substantial improvements over the Advance Notice of Proposed Rulemaking (ANPR) published by FDA on March 6, 1997 (62 Fed. Reg. 10242). The NPRM, for example, did not adopt the "therapeutic class" approach outlined in the ANPR. The NPRM also proposes that, in the case of multiple source or multiple strength products, at least two non-CFC products with the same active moiety be marketed before an essential use designation could be considered for removal. These changes from the ANPR, along with the requirement for notice and comment rulemaking before an essential use designation is removed, should help to ensure that patients are afforded adequate alternatives to their current therapies as well as involved in the process of making decisions on whether to remove essential use designations.

We also recognize that the NPRM attempts to balance difficult and sometimes competing priorities to protect patients while CFC-free products are developed and approved to meet their medical requirements. As the FDA testified before the Health and Environment Subcommittee on May 6, 1998 with respect to the ANPR, "It needs to be emphasized strongly that FDA is not proposing to accelerate the phaseout of CFC-based MDIs as has been suggested by some . . . Rather, consistent with national policy and our obligations under the Montreal Protocol and the

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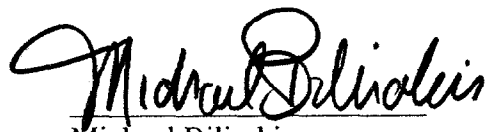
Clean Air Act, 42 U.S.C. 7671, FDA is working to develop a regulatory strategy by which such future determinations can be made once sufficient non-CFC alternative inhalation products become available in the United States; and the products are demonstrated to meet the needs of patients who currently rely on CFC-based MDIs." We further note that in response to comments received on the ANPR, FDA explicitly stated that "it is premature to set a specific timeframe for the elimination of all essential-use exemptions because too many variables exist as to when applications for new products will be submitted to the agency, when they will gain approval, and when the products might be considered clinically acceptable alternatives to CFC-MDIs."

We do have concerns, however, that under certain circumstances, new CFC-based MDIs may be approved by FDA although such devices may not offer new health benefits to patients or any improvement in MDIs utilized by patients. While we recognize that the FDA must balance many factors in constructing policies to determine the granting or denial of future essential use designations, we are concerned about the possible effect of such new approvals on the national transition strategy sought to be effectuated by the NPRM. It is possible that new CFC-MDIs could promote new patient reliance on products at the same time, or within a short timeframe, that reviews of the essentiality of such products would be taking place. This could add to confusion within the patient and health care community, as well as a possible disruption in therapy if essential use status is subsequently removed.

For these reasons, we would support further review by FDA of this issue during the public comment period for the NPRM. We believe one option would be for FDA to clarify whether it would require all new CFC MDIs to obtain a new important health benefit. Under the NPRM, new essential uses for commercially marketed drugs and investigational new drugs must provide an unavailable important public health benefit, but we understand that FDA may believe it is constrained regarding approval of products which do not involve a new essential use. We believe the 1990 Clean Air Act Amendments, which serve as legal authority for the NPRM, might also support an interpretation that such a requirement is inherent in the requirement that the use of CFC in medical devices be necessary.

Thank you in advance for taking our concerns into consideration.

Sincerely,



Michael Bilirakis
Chairman, Health and
Environment Subcommittee

Richard M. Burr
Member of Congress

Ron Klink
Ranking Member
Oversight and Investigations

Clifford Stearns
Member of Congress

Chris Smith
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