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February 11, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 03P-0029
Citizen Petition on Removal of Essential Use Designation for Albuterol

Dear Sir/Madame:

The US STAKEHOLDERS GROUP ON MDI TRANSITION, nine organizations representing patients with asthma, chronic obstructive pulmonary disease ("COPD") and other respiratory diseases, physicians specializing in the treatment of these diseases, respiratory therapists, and other healthcare professionals specializing in respiratory care, would like to thank the Food and Drug Administration (FDA) for publishing a timeline on which it will conduct rulemaking to remove metered-dose inhalers ("MDIs") containing the active moiety albuterol from the list of essential uses of ozone-depleting substances ("ODS"). We agree with FDA's tentative conclusion that albuterol meets the criteria for removal of an essential use, and we look forward to working with the Agency to determine what phaseout period length will minimize any adverse effects on patient health.

In light of FDA's pending action, the STAKEHOLDERS would like to take this opportunity to enter into the docket the attached Comments, recently submitted to the Fifteenth Meeting of the Parties to the Montreal Protocol. These Comments, among other things, indicate the STAKEHOLDERS' long-standing support for a 2005 end date for the use of CFC albuterol MDIs in the U.S. Our interest has always been in a smooth transition, and we applaud FDA's decision to act in order to protect U.S. patients from dependence on these "convicted chemicals" whose future manufacture, availability and cost are uncertain.

Of course, the US STAKEHOLDERS GROUP shares the Agency's interest in ensuring patients are not put at risk because HFA albuterol will cost more for some people than the CFC albuterol it replaces. Indeed, our petition requested prompt rulemaking so that the issue of price could be evaluated and addressed *before* scarcity or unavailability of CFCs could have any impact on transition. But we have never believed that questions about inhaler cost should or would prevent transition. Already one manufacturer has committed to freezing prices through 2007 and to distributing two million free HFA albuterol inhalers annually. These and other measures taken by manufacturers, as well as proper planning and education, can ensure all patients have access to the medicine they need.

03P-0029 C6

We look forward to the rulemaking and to assisting FDA plan and implement the transition timeline.

Sincerely,

Fran Du Melle
Senior Vice President
Convener, US STAKEHOLDERS GROUP ON MDI TRANSITION

Attachment: Comments of the U.S. STAKEHOLDERS GROUP ON MDI TRANSITION to the Fifteenth Meeting of the Parties to the Montreal Protocol

US STAKEHOLDERS GROUP ON MDI TRANSITION

COMMENTS ON THE ESSENTIAL USE OF CFCs IN METERED DOSE INHALERS (MDIs)

FIFTEENTH MEETING OF THE PARTIES (NAIROBI); 10-14 NOVEMBER 2003

As the Montreal Protocol Parties consider steps to promote closure of the essential use exemption for MDIs, the STAKEHOLDERS wish to express their support for the adoption of appropriate measures as outlined in Draft Decision XV/* submitted by the European Community, Promoting the closure of essential use nominations for metered-dose inhalers, specifically:

- the discontinuation after 2005 of essential use authorizations in developed countries for CFC volumes for MDIs containing the active ingredient salbutamol (albuterol);
- a target date for the discontinuation of essential use authorizations for CFC volumes in developed countries for any MDI products;
- the discontinuation of essential use authorizations for CFC volumes for MDI products where the manufacturer is not actively pursuing transition to CFC-free alternatives; and
- a narrow case-by-case exemption from the above if the CFCs are needed to manufacture MDIs shown to be clearly indispensable for patient care.

GLOBAL TRANSITION TARGETS

The STAKEHOLDERS consistently have supported the idea of a global framework for drawing the essential use process for MDIs to a close. We repeatedly have stressed the importance to patients of avoiding a transition to CFC-free MDIs that is dictated by market forces, scarcity or unavailability of specific products. Given the serious medical importance of MDIs, patients need the protection provided by a planned, orderly end to transition that is both fair and transparent. The EU proposal meets this objective by establishing firm targets and timetables, coupled with a narrow exception for any Party who demonstrates that CFCs are indispensable for patient care. We urge the Parties to adopt the measures proposed by the EU in order to bring much-needed transparency and order to the process.

The STAKEHOLDERS believe the specific target date of 2005 for ceasing new authorizations of CFCs for use in albuterol products makes sense for several reasons. First, there is no medical reason why patients would be adversely affected. Around the world, CFC-free alternatives are in widespread use, with no adverse impacts reported. In the U.S., two CFC-free alternatives have been on the market for close to two years. Second, the measures proposed by the EU – which concern overall essential use CFC authorizations – are not inconsistent with having specific product removal determined at the national level. The STAKEHOLDERS always have supported the right of each country to determine when and how individual products are removed from sale, but we do not take that to mean that a country can circumvent the essential use process by failing to implement transition in the face of overwhelming evidence that technical and economically feasible alternatives exist. In the case of albuterol, the EC's proposal to cease authorizing new quantities of CFCs after 2005 for salbutamol MDIs intended for developed country markets moves the developed world away from its dependency on CFCs without restricting any country's right to regulate its own market for MDI products.

As for an overall end date, the STAKEHOLDERS wish to reiterate their longtime support for the idea of a closure date for the essential use exemption. As stated above, patients should not be left unprotected from the risks of the marketplace and politics. There are simply too many uncertainties about long-term availability and uninterrupted supply of pharmaceutical-grade CFCs as well as of the thirty-plus components of increasingly outdated CFC MDI technology. In the face

of declining worldwide demand for CFCs generally, STAKEHOLDERS also are concerned that the economics of spreading fixed production costs among fewer and fewer CFC MDI units sold could lead manufacturers to withdraw products abruptly, or withdraw products that serve small niche markets based on profit margins, not patient need. Clarifying the timeline for transition is a safe way of limiting risk to patients, while at the same time providing transparency for Parties and manufacturers.

Although the Parties will need to consider many factors before settling on the 2007 date specifically, we believe it is a reasonable date for several reasons. First, 2007 seems technically plausible given that IPAC, the consortium of pharmaceutical manufacturers – including some companies that are not even on the market yet with HFA alternatives – has endorsed the 2007 date. As for U.S. patients specifically, 2007 is prudent given that the FDA, in its Final Rule implementing transition, designated 2005 as the date after which it gave itself authority to begin considering removal of ODS containing MDIs even if a CFC-free alternative with the same active ingredient is not available. In any event, the "escape clause" contained in the EC Draft Decision would protect patients by allowing authorizations of CFC volumes for products that are clearly indispensable for patient need.

ACTIVE PURSUIT AND OTHER ELEMENTS OF THE EC DRAFT DECISION

The STAKEHOLDERS agree with recent conclusions of TEAP that introduction and acceptance of HFA alternatives will not necessarily led to successful transition. Accordingly, we support additional measures at the Protocol level such as those outlined in paragraph 4 of the EC Draft Decision. Obligations on manufacturers to actively pursue development and dissemination of CFC-free treatments will complement the broader effort to define a timeline for transition. These types of measures also may help to align the rates of transition in individual countries, a factor TEAP recently noted has delayed closure.

The US STAKEHOLDERS GROUP ON MDI TRANSITION has long embraced the reality that the essential use exemption was designed to be temporary, to last only until acceptable alternatives were available. In fact, patients and physicians await transition as it offers the prospect of new and improved therapies as well as the opportunity to update individual disease management plans as patients are switched to CFC-free therapies. A comprehensive understanding of products available and expected -- together with a clear timeline for when CFCs will be eliminated -- will protect patients and the physicians who treat them. A smooth transition requires that decisions about the use of CFCs in MDIs be informed by patient need, not market forces.

Given the need to eliminate all ozone-depleting substances, and the commitment of the international community to achieve ozone layer recovery, the STAKEHOLDERS support measures to move patients away from dependency on CFCs as soon as is feasible. We therefore urge prompt adoption at MOP-15 of the measures proposed by the EU in order to promote a transparent and orderly transition away from CFC-containing MDIs.

CONTACT:
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THE US STAKEHOLDERS GROUP ON MDI TRANSITION is a consortium of leading patient and medical professional associations, representing more than 25 million Americans who suffer from asthma, chronic obstructive pulmonary disease (COPD), and other respiratory diseases. Since 1996, the STAKEHOLDERS have sought to ensure a transition to CFC-free MDIs that properly balances the threat to public health posed by stratospheric ozone depletion with the needs of patients who rely on inhaled therapies.