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Dockets Management Branch
Docket Number 2003P-0029
U.S. Food and Drug Administration
Room I-23
12420 Parklawn Drive
Rockville, MD 20857

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AUG 03 2004

CDR / CDER

Re: Comments Regarding Citizen Petition Submitted by the U.S. Stakeholders Group on MDI Transition (Docket Number 03P-0020)

Honeywell previously provided comments to this petition on April 20, 2004. Based on interpretations of our comments observed at the Montreal Protocol Open-Ended Working Group meeting in Geneva from July 13-16, 2004, we felt it important for us to clarify the statements we described for CFC supply for metered dose inhalers (MDIs) for albuterol.

In our April 20th communication, under the section addressing "Certainty of Future Supply" we stated that "MDI manufacturers normally carry strategic inventories of CFCs that, coupled with essential-use allowances for 2004 and 2005, should allow them to use Weert-made products until 2008. Honeywell is willing to work with albuterol MDI manufacturers to produce and store enough material from Weert to last them until 2008." The intent of the statement was for the FDA and the industry to take into account that the use of Weert-produced inventories could be stretched out until 2008, if additional time was necessary to transition to Baton-Rouge produced material.

We hereby submit a more detailed explanation and the assumptions behind our statement:

- Assume 41 million CFC-based inhalers are produced in the United States every year.
- Assume each inhaler has 20 grams of CFCs for the albuterol CFC product including yield losses
- Assume MDI manufacturers carry a strategic inventory of CFC propellant sufficient to meet half a year's production demand, or $820/2 = 410$ MT.
- In 2004, there is a total of 1445 metric tons of essential use allowances allocated to three companies that make albuterol. Assuming that the same number of metric tons are approved for 2005 as in 2004, that is a total of 2890 metric tons of essential use allowances that can be produced in these two years.
- 2890 metric tons of CFCs + 410 metric tons of strategic reserves = 3300 metric tons of CFCs. This amount of product should last $3740/820 = 4.02$ years, which is enough to last until 2008.

A key assumption in the above analysis is the 100% use of allocated essential use rights. The ATOC Progress Report in the May 2003 TEAP Progress Report cites CFC usage vs. rights for

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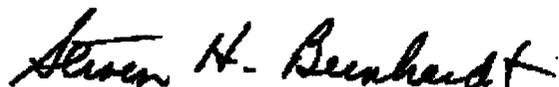
MDIs. For the period 1999-2002 an average of 74% of granted rights were used in the US with annual use ranging from 60%-91%. There is currently no mechanism by which Honeywell can produce CFCs absent essential use transfer from MDI producers holding those rights. Unless there is prompt regulatory and industry action to execute this plan, production of 2006 essential use allowances may be required, depending on when the FDA declares CFC- based albuterol MDIs non-essential.

Note that Honeywell is making no statements regarding the accuracy of its analysis or the appropriateness of this strategy. Honeywell is merely adding its analysis as a basis for consideration and discussion by industry, the FDA and EPA. Before such a plan would be implemented, Honeywell would expect the pharmaceutical industry, the FDA and EPA to validate the assumptions made above and production orders placed in time to execute this plan.

Honeywell's business plan is committed to produce CFCs for MDIs in our Baton Rouge facility. This is being done to supply propellant for the many non-albuterol CFC MDIs for which no viable commercial alternatives exist. An additional benefit is to provide a secure source of CFCs for albuterol for as long as needed.

We appreciate the opportunity to clarify our earlier statements to the FDA and hope that others involved in the CFC MDI issue can better appreciate our intentions, which is to provide security of supply for essential use CFCs. If there is need for further discussion or you need additional information, please contact me.

Sincerely,



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