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Dockets Management Branch
Docket Number 03P-0029
U.S. Food and Drug Administration
Room I-23
12420 Parklawn Drive
Rockville, MD 20857

Sent Via Facsimile to 301-827-6870

Re: **FDA Proposed Rule, Docket No. 2003P-0029**

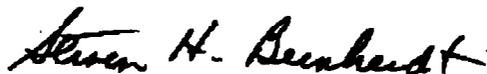
As we indicated we would do in an earlier docket submission, Honeywell is providing an update on CFC production at our Baton Rouge, LA facility as well as address comments to this same docket that raised questions regarding the production of chlorofluorocarbons ("CFC") for albuterol metered dose inhalers.

Honeywell has completed validation production runs of CFC-11 and -12 at its Baton Rouge, LA facility. Analyses of the product have been performed by Honeywell and show that this product meets the same quality criteria as material produced in the Weert, The Netherlands plant.

Supply of carbon tetrachloride ("CTC") is secure and of acceptable quality. A submitter to the docket commented that the use of carbon tetrachloride as a feedstock to manufacture CFCs is being eliminated by the Montreal Protocol. **However, Montreal Protocol exempts any ozone-depleting substance, such as carbon tetrachloride, that is used as a feedstock and undergoes a chemical transformation.** This is the case for production of CFCs and some other fluorocarbon products. There are currently two CTC suppliers in North America and at least three located in Europe. In addition to having a secure source for CTC that is used for direct manufacture of CFC-11 and -12, Honeywell produces an ozone-friendly fluorocarbon that requires CTC feedstock. This fluorochemical is not subject to phaseout by the Montreal Protocol and will represent a long-term demand for CTC. Based on our business planning and discussions with suppliers, we conclude that there will be sufficient CTC demand for CFCs and other fluorocarbons to justify its production long term. Honeywell is confident in the ability of its supply chain group to source feedstock CTC for CFC-11 and -12 manufacture well into the next decade and beyond if necessary.

Honeywell's cGMP process, including but not limited to Standard Operating Procedures and Quality Control, ensures that our products meet customer specifications. Honeywell intends to produce CFC-11 and -12 in a shared facility in Baton Rouge. A shared production facility requires both careful planning and maintenance to eliminate any possibility of cross-contamination. Rigorous change-over procedures are standard. Currently, pharmaceutical grade CFC-114 is manufactured in Baton Rouge using shared production capacity. In fact, FDA inspected our CFC-114 production line in 2002 and found no issues with our operation. A shared facility allows for efficient utilization of assets to better control production costs while providing continuous supply as demand drops due to the inevitable CFC phase-out. Our experiences with shared plants make us confident in our ability to make CFC-11 and -12 without issue. In fact, such campaign production schemes are common practice in the pharmaceutical industry and present no problems when properly administered.

Sincerely,



Steven H. Bernhardt PhD
Global Director Regulatory Affairs
Honeywell Chemicals

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