



August 16, 2004

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

Re: Comments Regarding Citizen Petition Submitted by the U.S. Stakeholders Group on MDI Transition (Docket Number 2003P-0029)

These comments are submitted on behalf of Honeywell International Inc., in response to questions raised regarding Honeywell's ability to produce chlorofluorocarbon 11 and 12 ("CFC-11/12") at Honeywell's Baton Rouge, Louisiana facility. Commenting on behalf of Honeywell, the Company would like to reaffirm that if CFC 11/12 continue to be approved for "essential uses" in medical dose inhalers ("MDI") under the Montreal Protocol and the applicable EPA regulations Honeywell intends to continue to provide pharmaceutical grade CFC-11/12 to supply its pharmaceutical customers for this application.

Honeywell currently produces pharmaceutical grade CFC-11/12 for MDIs at its Weert, the Netherlands, facility but is in the process of consolidating CFC production at its Baton Rouge, Louisiana facility where Honeywell currently produces pharmaceutical grade CFC-114 and where Honeywell historically produced CFC-11/12 until 1996. In a letter to the Administrator of the Environmental Protection Agency, the Natural Resources Defense Council ("NRDC") has argued that Decision VII/9 under the

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Montreal Protocol would prohibit Honeywell from retransferring its CFC-11/12 production from the Weert facility back to its Baton Rouge facility. After extensive review and consideration, Honeywell believes that under applicable law, the Company may continue to produce pharmaceutical grade CFC-114 at the Baton Rouge facility and may recommence manufacture of pharmaceutical grade CFC-11/12 for which it has properly-issued MDI allowances.

While generally prohibiting the production of CFCs after 1995, the Montreal Protocol and applicable EPA regulations specifically include two separate and distinct exceptions that allow for continued production of CFCs for two specific purposes. The first allows for production for “essential uses” of developed countries and the second allows production to satisfy the “basic domestic needs” of Article 5 developing countries. Under these two exceptions, Honeywell may appropriately continue to produce CFCs. Specifically at issue in this petition is Honeywell’s ability to continue to produce pharmaceutical grade CFCs for MDIs as “essential uses.”

1. “Essential Use” Exception

Under the U.S. Clean Air Act, Honeywell may produce CFC-11/12 in the U.S., so long as it has production allowances based on an “essential use” authorization that has been properly allocated to a pharmaceutical company and subsequently conferred to Honeywell. Section 604(b) of the Clean Air Act provides that, notwithstanding the general prohibition of production of CFCs, the Administrator must authorize the production of limited quantities of CFCs for use in MDIs if the Commissioner of the Food and Drug Administration (FDA), in consultation with the EPA Administrator, determines that such production is necessary for use in medical devices. EPA regulations

likewise allow production to meet “conferred unexpended essential-use allowances.” 40 CFR §82.4(b).

“Essential use” allowances are determined annually through a multi-step process that involves an EPA notice requesting information related to “essential uses,”¹ and an FDA decision whether the proposed use is truly an “essential use.”² When these decisions are complete, the United States submits its nominations for essential uses to the Ozone Secretariat to be considered at the next Meeting of the Parties (MOP). If these nominations are approved, EPA promulgates a rule that allocates the “essential uses” approved at the MOP among the relevant entities.³ Once a pharmaceutical company receives its allocation, it confers production rights on a manufacturer such as Honeywell. In the past, Honeywell has manufactured CFC-11/12 under these production rights in its Weert facility. In the future, manufacturing will occur in Baton Rouge, where Honeywell previously manufactured CFC-11/12, and currently manufactures CFC-114.

2. Decision VII/9 Basic Domestic Needs

The NRDC letter cites Decision VII/9 governing production for Basic Domestic Needs as the basis for its argument that Honeywell may not recommence production of CFC-11/12 at its Baton Rouge facility. Decision VII/9 governing the production of CFCs for basic domestic needs of Article 5 developing countries states that “from December 7, 1995 no Party should install or commission any new capacity for production” of CFCs. Decision VII/9 does not prohibit properly authorized production at Honeywell’s Baton Rouge, LA, plant, for several reasons.

¹ For example, the most recent notice is published at 68 Fed. Reg. 59,170 (Oct. 14, 2003)

² See 42 U.S.C. § 7671(d)(2).

³ See, e.g., 69 Fed. Reg. 4059 (Jan. 28, 2004).

First, Decision VII/9 by its terms does not apply to “essential use” production under the Montreal Protocol. Decision VII/9 is entitled “Basic Domestic Needs” and relates to CFC manufacture for Article 5 developing countries, not to manufacture for “essential uses.” It expresses the Parties’ desire to prohibit new CFC capacity for production for Article 5 countries, not production of pharmaceutical grade CFCs for “essential use” production for developed countries. As outlined above, there is a separate and distinct approval process that governs production for “essential uses”.

Second, nothing in Title VI of the Clean Air Act or applicable EPA regulations restricts production by those who hold “essential use” allowances based on whether or not “new capacity” would be required. Indeed, the phrases used by NRDC in its letter – “new capacity,” commission,” decommission,” mothball” – do not appear at all in the applicable EPA regulations. 40 CFR Part 82, Subpart A.

Third, no new production capacity or commissioning is necessary for Honeywell to produce CFC-11/12 in Baton Rouge. Although Honeywell transferred its production of its CFC 11/12 product to Weert in 1996 no equipment outages or mothballing occurred. Rather, Honeywell continues today to produce pharmaceutical grade CFC-114 at the Baton Rouge Facility which is sold to pharmaceutical customers with properly issued “essential use” allowances. CFC production at Baton Rouge has not been “mothballed” or otherwise out of service. Thus the express terms of Decision VII/9 – “install or commission any new capacity” – do not apply to the Baton Rouge facility, even if the Decision were applicable.

Honeywell hopes that these comments will be helpful as the FDA considers this important issue. My client or I are available to answer any further questions of the FDA on this matter.

Sincerely yours,

A handwritten signature in black ink that reads "Richard Ayres". The signature is written in a cursive style with a large, sweeping flourish that loops under the name.

Richard E. Ayres
Ayres Law Group