

this reason, EPA has not placed the responses in the docket.

2. On April 17, 2003, EPA sent FDA the information MDI manufacturers provided in response to the 114 letters with a letter requesting that FDA make a determination regarding the amount of CFCs necessary for MDIs for calendar year 2003. This letter is available for review in Air Docket ID No. OAR-2003-0202.

3. On August 25, 2003, FDA sent a letter to EPA stating the amount of CFCs necessary for each MDI company in 2004. This letter is available for review in the Air Docket ID No. OAR-2003-0202.

In their letter, FDA informed EPA that they had determined that 2,077.91 metric tons of CFCs were necessary for use in medical devices in 2004. The letter stated, "Our recommendation for the allocation for CFCs is lower than the total amount requested by sponsors. In the past, we have based our recommendations on estimates that 60 million albuterol MDIs using CFCs as a propellant would be necessary each year. However, we have based the recommendation for 2004 on an estimate that 55 million will be necessary. In reaching this estimate, we took into account the sponsors' production of albuterol MDIs that used CFCs as a propellant in 2002, their

estimates for production in 2003, and the presence on the market of two albuterol MDIs that do not use CFCs. Three firms have requested CFCs sufficient to manufacture a total of over 65 million albuterol MDIs. Our allocation decision is based on a need to limit CFC allocations to quantities needed for the manufacture of 55 million albuterol MDIs and ensure the public health."

In accordance with the determination made by FDA, today's action proposes to allocate essential use allowances for a total of 2,077.91 metric tons of CFCs for use in MDIs for calendar year 2004. The amounts listed in this proposal are subject to additional review by EPA and FDA if new information demonstrates that the proposed allocations are either too high or too low. Commentors requesting increases or decreases of essential use allowances should provide detailed information supporting their claim for additional or fewer CFCs. Any company that needs less than the full amount listed in this proposal should notify EPA of the actual amount needed.

IV. Exemption for Methyl Chloroform for Use in the Space Shuttle and Titan Rockets

As discussed in Section I.C above, before the start of calendar year 2005; EPA may allocate up to 176.4 tons of

methyl chloroform for authorized essential uses. According to reporting submitted to the EPA tracking system for ozone-depleting substances, the total amount of methyl chloroform produced or imported by essential use allowance holders (the U.S. Air Force (USAF) for Titan Rockets, and the National Aeronautics and Space Administration (NASA) for the Space Shuttle) from 1999 through the second quarter of 2003 was 34.523 metric tons. USAF and NASA have notified EPA that they do not intend to use their 2003 allowances to obtain methyl chloroform during the last two quarters of 2003. Therefore, EPA finds that 141.877 tons of methyl chloroform allowances are available for 2004. In addition, USAF has notified EPA that they have no need for 2004 allowances. For this reason, we propose to make the remaining balance of allowances (141.877 metric tons) available to NASA.

V. Proposed Allocation of Essential Use Allowances for Calendar Year 2004

EPA proposes to allocate essential use allowances for calendar year 2004 to the entities listed in Table 1. These allowances are for the production or import of the specified quantity of class I controlled substances solely for the specified essential use.

TABLE 1.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2004

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC-11 or CFC-12 or CFC-114	390.60
Aventis Pharmaceutical Products	CFC-11 or CFC-12 or CFC-114	48.40
Boehringer Ingelheim Pharmaceuticals	CFC-11 or CFC-12 or CFC-114	500.20
PLIVA Inc.	CFC-11 or CFC-12 or CFC-114	136.00
Schering-Plough Corporation	CFC-11 or CFC-12 or CFC-114	918.00
3M Pharmaceuticals	CFC-11 or CFC-12 or CFC-114	84.71
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/ Thiokol Rocket.	Methyl Chloroform	141.877

VI. Correction to 40 CFR Part 82, Sections 3 and 4(k)

On January 2, 2003, EPA published a final rule (68 FR 237) regarding quarantine and preshipment applications of methyl bromide, which is an ozone-depleting substance. This final rule removed paragraphs (n) through (s) of 40 CFR Part 82, Section 4, and redesignated paragraphs (t) through (w) as (n) through (q). However, the final rule did not also change the definition of "essential-use allowances" in § 82.3 to be consistent with the reordering of paragraphs in § 82.4. The

definition of essential use allowances in § 82.3 reads, "Essential-Use Allowances means the privileges granted by § 82.4(t) to produce class I substances, as determined by allocation decisions made by the Parties to the Montreal Protocol and in accordance with the restrictions delineated in the Clean Air Act Amendments of 1990." Therefore, for consistency with the reordered regulations, we are correcting the definition of essential use allowances to refer to § 82.4(n).

In addition, the final rule revised section 4(k) of 40 CFR Part 82 to include

paragraph 4(k)(1), which states that "* * * only essential-use allowances or exemptions are required to import class I controlled substances, with the exception of transshipments, heels, and used controlled substances." In undertaking this revision, EPA inadvertently deleted a phrase that had appeared in the prior version of this statement. EPA proposes to restore the deleted phrase by correcting the statement in question to read, "* * * only essential use allowances or exemptions are required to import class I controlled substances, with the