ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6929–6]

RIN 2060–AJ33

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2001: Allocation for Metered Dose Inhalers and the Space Shuttle and Titan Rockets

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this action, EPA is allocating essential use allowances for stratospheric ozone depleting substances for calendar year 2001. EPA allocates essential use allowances to an applicant for exempted production or import of a specific quantity of class I ozone depleting substances solely for the designated essential use. Essential use allowances permit a person to obtain controlled substances as an exemption to the January 1, 1996 regulatory phase-out of production and import of these substances. Today, EPA is allocating essential use allowances for the production and/or import of class I substances for use in medical devices for the treatment of asthma and chronic obstructive pulmonary disease, and for use in the Space Shuttle and Titan Rockets for calendar year 2001. With today's action, EPA is also amending the regulations to allow essential use allowances for medical devices to be transferred among essential use allowance holders. The essential use exemption for class I ODSs for laboratory and analytical applications will be addressed in a separate rulemaking.

DATES: This action is effective January 8, 2001.

ADDRESSES: Materials relevant to this rulemaking are contained in Docket No. A–93–39. The Docket phone is (202) 260–7548 and is located in Waterside Mall, Room M–1500, 401 M Street, SW., Washington, DC, 20460. The materials may be inspected from 8 a.m. until 5:30 p.m. Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: The Stratospheric Ozone Protection Hotline at 1–800–296–1996 or Erin Birgfeld, U.S. Environmental Protection Agency, Global Programs Division, Office of Atmospheric Programs, 6205J, 1200 Pennsylvania Avenue N.W., Washington, DC, 20460; telephone (202) 564–9079; fax: (202) 565–2095; email: birgfeld.erin@epa.gov.

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I. Background

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is the international agreement to reduce and eventually eliminate production and consumption[1] of all stratospheric ozone depleting substances (ODSs). As of January 1996, production and import of class I ODSs (except methyl bromide) were phased out in all developed countries, including the United States. However, the Protocol and the Clean Air Act (CAA or Act) provide exemptions that allow for the continued import and/or production of class I ODSs for specific uses. Under the Montreal Protocol, exemptions are granted for uses that are determined by the Parties to be ''essential'' as defined by Decision IV/25. The procedure set out by Decision IV/25 first calls for individual Parties to nominate essential uses. The Protocol's Technology and Economic Assessment Panel (TEAP or the Panel) evaluates the nominated essential uses and makes recommendations to the Protocol Parties. The Parties make the final decisions on essential use nominations at their annual meeting.

EPA is responsible for allocating essential use allowances (EUAs) at the domestic level through rulemaking in accordance with provisions in the CAA. The CAA provides a specific exemption from the phase-out of class I ODSs at section 604(d)(2) that allows for the continued import and production of CFCs for use in medical devices. Today's action allocates EUAs for CFCs for use in metered dose inhalers (MDIs) for the treatment of asthma and chronic obstructive pulmonary disease (COPD) for calendar year 2001. EPA is also allocating methyl chloroform for use in the Space Shuttle and the Titan Rocket for calendar year 2001 under the authority of the statutory phase-out at section 604(a). Today's action also amends the regulations at 40 CFR 82.12 to allow transfer of EUAs for CFCs among MDI companies who hold essential use allowances.

Overview of the Notice of Proposed Rulemaking

The Notice of Proposed Rulemaking (NPRM) proposing to allocate essential use allowances for calendar year 2001 was published on October 6, 2000 (65 FR 59783). In the NPRM, EPA proposed to allocate CFCs for use in metered dose inhalers (MDIs) and methyl chloroform for use in the Space Shuttle and Titan Rocket. EPA proposed to allocate a total of 3098.67 metric tons of CFCs, which is the quantity that the Food and Drug Administration (FDA), in consultation with EPA, determined to be ''necessary'' for use in MDIs. The total amount of essential use authorizations for MDIs granted to the U.S. by the Parties to the Montreal Protocol for 2001 is 3,101 metric tons. We explained in the NPRM that it would not be possible to allocate CFCs in an amount higher than allocated to the U.S. by the Parties to the Protocol. EPA also proposed changes to the regulations at 40 CFR 82.12 that would allow transfer of EUAs for CFCs among essential use holders. We also proposed to allocate 60.1 metric tons of methyl chloroform (MCF) for use in the Space Shuttle and Titan Rockets.

EPA received a total of eight comments on the NPRM. Six comments were from individual companies who produce MDIs,[2] one was from a consortium group that represents MDI manufacturers,[3] and one was from Friends of the Earth. Three commenters expressed support for the provision to allow transfer of EUAs for CFCs between allowance holders. One commenter requested additional EUAs to meet their projected needs for MDI production in 2001 without utilizing their strategic reserves. Two companies requested that their EUAs be reapportioned between them, but in the aggregate did not request an increase in EUAs. One commenter stated that EPA and FDA had improperly interpreted the

[1] ''Consumption'' is defined as the amount of a substance produced in the United States, plus the amount imported, minus the amount exported to Parties to the Montreal Protocol (*see* section 601(6) of the Clean Air Act). Stockpiles of class I ODSs produced prior to the 1996 phase-out can continue to be used for purposes not expressly banned at 40 CFR part 82, subpart C—Ban on Nonessential Products Containing Class I Substances and Ban on Nonessential Products Containing or Manufactured with Class II Substances.

[2] Pharmaceutical companies who commented were the following: Aventis Pharmaceuticals, 3M Pharmaceuticals, Boehringer Ingelheim Pharmaceuticals Inc., Schering Corporation, Sidmak Laboratories Inc., Glaxo Wellcome.

[3] The International Pharmaceutical Aerosol Consortium represents the following companies: AstraZeneca, Boehringer Ingelheim, Celltech-Medeva, Cheisi Farmaceutici, Glaxo Wellcome, and Norton Healthcare.

exemption for medical devices in the Act, and should not allocate CFCs for MDI products where an alternative propellant is available. Another commenter stated that the Act does not require EPA to transfer to FDA the responsibility to determine the amount of the allocation for CFCs, and that the FDA decision making process for determining the amount of CFCs necessary should be more transparent. EPA will summarize and address all comments in the body of this preamble. There were no comments on the proposed allocation of MCF for use in the Space Shuttle and Titan Rockets.

How Do the Parties to the Montreal Protocol Define an ''Essential Use''?

Decision IV/25 of the Parties to the Montreal Protocol set forth the criteria for determining whether a particular use of class I ODS is ''essential'' and would thus be eligible to receive EUAs for controlled substances. This decision states the following:

''(1) that a use of a controlled substance should qualify as 'essential' only if:

(i) It is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

(ii) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;

(2) that production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(i) all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and

(ii) the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances.''

What Was the International Procedure for Approving Essential Use Exemptions for the Year 2001?

The international process for nominating and approving essential use allowances for the year 2001 occurred in the same way as in prior years. The companies in Table I submitted applications either on their own or as a part of the International Pharmaceutical Aerosol Consortium (IPAC), requesting class I ODSs for essential uses in response to the August 10, 1998 **Federal Register** document (63 FR 42629). Their applications requested exemptions for the production and import of specific quantities of certain class I controlled substances after the phase-out, and provided information in accordance with the criteria in Decision IV/25 of the Protocol and the procedures outlined in the ''1997 Handbook on Essential Use Nominations.'' EPA reviewed the applications and nominated these uses to the Protocol Secretariat for consideration by the Technical and Economic Assessment Panel (TEAP) and its Technical Options Committees. MDI producers requested a total of 3,101 metric tons of CFCs for use in 2001. The Parties to the Montreal Protocol approved this amount as essential for the U.S. for 2001 at the Eleventh Meeting in 1999 (Decision XI/14). On September 15, 1999, EPA issued another notice requesting supplemental applications for essential use allowances for the year 2001 and beyond (64 FR 50083). No company requested a supplemental amount of CFCs for the year 2001 at that time.

How Does the Clean Air Act Authorize Essential Use Allowances for MDIs?

Section 604(d)(2) of the CAA provides a standing exemption to the phase-out of class I ODSs for the production and importation of CFCs for use in medical devices which reads:

> ''Notwithstanding the termination of production required by subsection (b), the Administrator, after notice and opportunity for public comment, shall, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of class I substances solely for use in medical devices if such authorization is determined by the Commissioner, in consultation with the Administrator, to be necessary for use in medical devices.''

Section 601(8) of the Clean Air Act defines the term ''medical device'' and states the following:

> [A]ny device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system—
>
> (A) if such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner [of FDA]; and
>
> (B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner [of FDA] in consultation with the Administrator [of EPA].

As discussed in the NPRM, EPA is relying on FDA regulations at 21 CFR 2.125 to provide determinations of whether a ''safe and effective alternative'' is available for any particular CFC MDI. It should be noted that FDA approval of a non-CFC product is a determination that the product is safe and effective, but it is not a determination that the product is a ''safe and effective alternative'' for any other CFC MDI product under the Act. FDA states in their notice of proposed rulemaking on essential use determinations that ''a non-CFC product simply having the same active moiety as a CFC product is only one factor to be considered. Other factors, such as whether the non-CFC product has the same route of administration, the same indication, and can be used with approximately the same level of convenience, are important considerations. Additionally, FDA must consider whether patients who medically need the CFC product are adequately served by the non-CFC product.'' (September 1, 1999, 64 FR 47735). While FDA has approved two non-CFC MDIs as of December 1, 2000, FDA has yet not identified any ''safe and effective alternative'' to any CFC MDI as specified by section 601(8)(A). Thus, part (A) of the definition of medical device has been met, and is consistent with today's rulemaking.

With respect to section 601(8)(B), EPA is relying on current FDA regulations (21 CFR 2.125) listing medical devices that FDA has found to be essential. The companies for which EPA is granting essential use allowances produce CFC MDIs covered by this regulation. Thus, the products for which EPA is granting essential use allowances are ''determined to be essential'' by FDA.

One commenter stated that under section 601(8)(A), EPA must determine that no safe and effective alternative propellant exists for any MDI to meet the definition of ''medical device.'' EPA believes that the phrase ''safe and effective alternative'' at section 608(1)(A) does not refer an alternative propellant, but refers to a ''safe and effective alternative'' to a CFC MDI. This is because FDA only approves MDIs under a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) as a whole unit and not by approving each of its components. Therefore, it is impossible for FDA to approve an alternative to the class I or class II substance (*i.e.* the propellant) alone, and it is reasonable to conclude that the phrase ''safe and effective alternative'' refers to an adequate replacement for the CFC MDI product.

This commenter also quoted a passage from the legislative history of the 1990 Amendments which states that ''unless a safe substitute exists or until a

substitute is developed and approved by FDA, a drug delivery system may be found by the Commissioner and the Administrator to be essential'' (S. Rep No. 228, 101st Cong., 1st Sess. 1989, 1990). The commenter believes that this passage supports their belief that once a drug containing a safe and effective alternative propellant has been approved by FDA, FDA has no authority to continue to designate analogous CFC-containing products as ''essential''. In response, we note that the term ''drug delivery system'' indicates that Congress envisioned that FDA would need to approve an entire non-CFC drug delivery system, and not just the alternative propellant. Further, the use of the term ''substitute'' indicates that Congress was looking to FDA to determine whether a non-CFC MDI is a safe and effective replacement for a particular CFC MDI (*i.e.* a ''safe and effective alternative''). While this report refers to Senate language which is somewhat different from what appears in the 1990 Amendments, the Senate's intent, revealed by this passage is consistent with EPA and FDA's interpretation of the Act.

The commenter also states that the safety and efficacy of alternatives to CFCs is determined by EPA under section 612 of the CAA, and that EPA had stated that it would rely upon FDA's approval of medical products containing alternative propellants under the Food Drug and Cosmetic Act (FDCA) for a determination that there are no human health effects from the use of the alternative propellant. Thus, the commenter believes that when FDA approves a non-CFC MDI as safe and effective under the FDCA, EPA must conclude that the non-CFC propellant in that product is safe and effective for the purposes of the CAA. In fact, EPA has already reviewed the health risks associated with alternative aerosol propellants for use in non-CFC MDIs under section 612 of the Act. Nevertheless, EPA disagrees with the assertion that a determination that an alternative propellant to an ODS is acceptable under section 612 of the Act has any bearing on the determination of whether a non-CFC MDI is a ''safe and effective alternative'' to a CFC MDI as required by section 601(8)(A).

The commenter states that when a non-CFC MDI is approved under the FDCA, only CFC-based products containing the same active moiety, and the same labeled indications would no longer qualify as ''medical devices'' under the Act, and that in instances where the labeled indications of a non-CFC drug do not fully duplicate those of a CFC product, EPA may only authorize production of limited quantities of CFCs that the EUA applicant demonstrates are necessary to serve patients not covered by the non-CFC drug product's indications. EPA believes that the commenter is wrong to assert that because a safe and effective non-CFC MDI is available, EPA should deem CFC MDIs with the same active moiety to be non-essential for the purposes of the CAA. As stated earlier, FDA approval of a non-CFC product is a determination that the product is safe and effective, but it is not a determination that the product is a safe and effective alternative for any other product under the Act. Because FDA has yet not identified any ''safe and effective alternative'' for any CFC MDI, today's allocation of CFCs for essential uses remains consistent with section 601(8)(A).

The commenter's suggestion that EPA make medical decisions regarding whether a non-CFC MDI is an adequate alternative to a CFC MDI produces a result that would put asthma patient health at risk. FDA is the appropriate agency with expertise to make independent medical decisions that directly affect patients. The determination that a CFC MDI is no longer ''essential'' is not, as the commenter suggests, one where EPA could merely look at the active moiety of the product, read the non-CFC product indication, compare it to the CFC MDI product indication, and determine any CFC MDIs to be non-essential. FDA states in their notice of proposed rulemaking on essential use determinations that ''a non-CFC product simply having the same active moiety as a CFC product is only one factor to be considered. Other factors, such as whether the non-CFC product has the same route of administration, the same indication, and can be used with approximately the same level of convenience, are important considerations. Additionally, FDA must consider whether patients who medically need the CFC product are adequately served by the non-CFC product.'' (September 1, 1999, 64 FR 47735). Most of these factors are not addressed on the indication label of an MDI. Thus the indication label alone cannot be used as the basis for determining whether a non-CFC product is an adequate alternative for any CFC MDI.

We believe that the overall purpose of the language in the Act regarding medical devices is to ensure that EPA's mission of environmental protection does not conflict with FDA's mission of protecting the patient health. Consistent with this purpose, we believe that in drafting the definition, Congress was focusing on the availability of adequate alternative medical treatment for patients who rely on CFC MDIs. EPA is not the appropriate agency to decide whether such alternative medical treatment is available. We do not believe that Congress intended EPA to make decisions involving medical judgement and expertise. On such questions, we have and will continue to defer to FDA.

The commenter states that FDA must approve and determine that the CFC-containing MDI is essential after notice and an opportunity for public comment, and asserts that once a drug containing a safe and effective alternative propellant has been approved by FDA, FDA has no authority to continue to designate analogous CFC-containing products as ''essential''. Further, the commenter states that EPA may not wait for FDA to remove that product from its list of essential uses before finding that it no longer qualifies as a ''medical device'' under the Act. Again, EPA believes that this interpretation of the Act is flawed. This is because section 601(8)(B) refers to approval of an alternative as occurring after ''notice and opportunity for comment.'' Because FDA does not approve alternative propellants, and because approval of a specific MDI drug product through the New Drug Application or Abbreviated New Drug Application system under the FDCA involves unilateral action by FDA without notice-and-comment rulemaking or consultation with EPA, it is reasonable to conclude that section 601(8)(B) refers to FDA's approval of an essential use listing in 21 CFR 2.125 which does involve notice and comment rulemaking. Thus, EPA believes that by allocating CFCs for products covered by the list of ''essential'' products at 21 CFR 2.125, we have fulfilled the requirements of section 601(8)(B).

Finally, the commenter states that FDA cannot use the categorical exemptions at 21 CFR 2.125 created more than twenty years ago to establish the essentiality of particular CFC MDI under the statute today, and that by doing so EPA and FDA are not relying on standards adopted under the Act in 1990. EPA believes that our explanation of this issue in the interim final rule allocating essential use allowances for calendar year 2000 still stands (see 65 FR 716, January 6, 2000).

While we are aware that FDA is currently engaged in rulemaking to revise its essential use regulations, we are relying on FDA's current essential use list at 21 CFR 2.125 for purposes of today's action. The statute does not specify a particular time at which FDA must make such a determination or

invalidate determinations made prior to the date of the 1990 CAA Amendments. Additionally, the 1990 CAA Amendments use language consistent with FDA's regulations at 21 CFR 2.125. We presume that Congress was aware of FDA's regulations when it passed the 1990 Amendments to the CAA. Therefore, we believe that the current essential use list remains valid. If FDA revises its regulations, we will take the revised list into account in future allocation decisions. EPA further notes that both EPA and FDA are implementing the more stringent provisions of the Montreal Protocol as specified by section 614(b) of the Act [4] by following the essentiality determinations of the Parties to the Montreal Protocol in allocating new CFCs.

How Does the CAA Authorize the Exemption for Methyl Chloroform?

With today's action, EPA is allocating methyl chloroform (MCF) for use in the Space Shuttle and Titan Rockets under the statutory phase-out schedule at section 604(a). This section provides that MCF may be produced at up to 20 percent of the amount produced in 1989 (the baseline year as specified at section 601(2)(B) of the Act). EPA is allocating a total of 60.1 metric tons of MCF, an amount well below 20% of the baseline year production of 315,169 metric tons for MCF (defined at 40 CFR 82.6).

Section 604(a) of the Act requires the complete phase-out of production of MCF after 2001. As a result, it is likely that EPA will be required to rely solely upon the exemption under section 604(d)(1), that may already be applicable, for the year 2002 and beyond. This exemption reads as follows:

(1) Essential Uses of Methyl Chloroform.—Notwithstanding the termination of production required by subsection (b), during the period beginning on January 1, 2002, and ending on January 1, 2005, the Administrator, after notice and opportunity for public comment, may, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of methyl chloroform solely for use in essential applications (such as nondestructive testing for metal fatigue and corrosion of existing airplane engines and airplane part susceptible to metal fatigue) for which no safe and effective substitute is available.

EPA understands that research on alternatives is progressing well, and that in the year 2002 there may be no need for an essential use exemption for MCF. Nevertheless, EPA believes that section 604(d)(1) may allow for the continued limited use of methyl chloroform for Space Shuttle and Titan Rocket through 2004 under the essential use exemption as long as no substitute is available.

II. Allocation Process for CFCs for Use in Medical Devices for the Year 2001

As explained earlier, section 604(d)(2) of the Act provides that EPA shall authorize production and import of limited quantities of class I substances for use in medical devices if FDA, in consultation with EPA, determines such authorization to be ''necessary.'' Thus, EPA in order to implement the exemption for medical devices must receive a formal determination on the amount of CFCs necessary for use in MDIs from FDA. FDA sent EPA a letter dated September 6, 2000 that provided their determination on the amount of CFCs necessary, and explained the bases for that determination.

One commenter stated that the CAA does not delegate to FDA the authority to dictate the nomination quantity and allocation of class I substances for medical devices. Rather, according to the commenter, the CAA requires that EPA shall consult with FDA only as to whether the authorization of class I substances for medical devices is necessary, which requires a yes/no determination only. Thus, EPA should not transfer to the FDA the responsibility to determine the quantity of essential use allowances allocated to companies.

EPA has addressed the comment that is raised here in the preamble to essential use allocation for calendar year 2000 (65 FR 40524, 40530–40537). We believe that the same interpretation and explanation provided in the previous rulemaking is applicable here. Section 604(d)(2) states the following: ''The Administrator, after notice and opportunity for public comment, shall, to the extent such action is consistent with the Montreal Protocol authorize the production of limited quantities of class I substances solely for use in medical devices if such authorization is determined by the Commissioner [of FDA], in consultation with the Administrator [of EPA], to be necessary for use in medical devices.'' (emphasis added) EPA believes that it is clear that the authorization in question is not for an indefinite amount but for ''limited quantities.'' It is equally clear that the subject of the Commissioner's determination of necessity is ''such authorization.'' Thus, if the latter part of the text quoted above were written in the active voice, it would say: ''if the Commissioner, in consultation with the Administrator, determines such authorization to be necessary for use in medical devices.'' We note that the expression ''such authorization'' refers back to the phrase ''authorize the production of limited quantities of class I substances solely for use in medical devices.'' Thus, the Commissioner of FDA must consider not only whether any production is necessary, but what quantity of production is necessary for MDIs.

Further, although EPA does have some data on CFC usage (which is shared with FDA), only FDA personnel are privy to confidential business information regarding annual sales and distribution of MDIs. This provides FDA with more complete knowledge of the MDI market than EPA. Because of FDA's access to additional information, and their medical expertise which is integral to making decisions that serve to protect the public health, EPA believes it is consistent with Congressional intent to consult with FDA in making decisions regarding the amount of CFCs necessary for the production of MDIs.

The commenter's second point was that EPA should ensure that the rationale for adjustments made to allocations and the bases for FDA recommendations are open and available to the public for review and comment. EPA agrees that the allocation process should be as transparent as possible while accounting for the confidential nature of the data employed to make the determination on the amount of CFCs necessary. To this end, EPA and FDA planned a process described in the NPRM that we felt would allow this determination on the amount of CFCs necessary to occur as openly as possible. EPA sent letters pursuant to section 114 of the Act to each essential use applicant requesting specific information such as the number of units of each product produced in previous years, the number of units produced in the first quarter 2000, the gross target fill weight per unit, the total amount of CFCs to be contained in the product in 2001, the number of units of each product anticipated to be produced in 2001, the additional amount of CFCs necessary for production, and the total amount of CFCs requested for each product in 2001. FDA, in consultation with EPA, based the determination of necessary amounts and the allocation on this information. Thus, each company knows what information it has submitted as the basis for its own allocation while protecting against disclosure of confidential business information to competitors. Finally, we placed all non-confidential materials in

[4] Section 614(b) states that ''* * * in the case of conflict between [the Act] and any provisions of the Montreal Protocol, the more stringent provision shall govern.''

the docket, including the FDA letter of September 6, 2000 that provided EPA with their recommendation on the amount of CFCs necessary for MDIs for the year 2001.

III. Allocation of Essential Use Allowances for Calendar Year 2001

EPA is allocating essential use allowances for calendar year 2001 to entities listed in Table I for exempted production or import of the specific quantity of class I controlled substances solely for the specified essential use. The allocation of CFCs for use in MDIs reflects the determination on the amount of CFCs ''necessary'' as specified under section 604(d)(2) of the Act taking into account two companies requests for reapportioning EUAs among them.

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2001

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease (in metric tons)		
Medeva, Armstrong Pharmaceuticals Inc.	CFC–11 or CFC–12 or CFC–114	189.00
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	338.36
Glaxo Wellcome Inc.	CFC–11 or CFC–12 or CFC–114	858.10
Aventis Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	190.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	304.51
Sidmak Laboratories/Medisol Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	192.20
Schering Corporation	CFC–11 or CFC–12 or CFC–114	1025.20
Sciarra Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	1.30
(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	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

Was the Allocation Listed in This Proposed Rule Changed in the Final Rule?

The total amount of CFCs allocated for use in MDIs is the same as in the proposed rule. However, the amount of EUAs allocated to two MDI companies was reapportioned between them at their request. One commenter is the New Drug Application (NDA) holder, and the other is a contract filler for that NDA holder. The NDA holder stated that they had reassessed the amount of MDIs the contract filler would produce for them in 2001. The NDA holder requested that a certain amount of EUAs allocated to their contract filler and earmarked for the production of the NDA holder's products be re-apportioned back to the NDA holder. The contract filler provided comments that supported the transfer of EUAs from them to the NDA holder (this contract filler is also an essential use allowance holder with its own allocation for production of its own MDIs). EPA believes that in this case, it is not necessary for FDA to approve this adjustment to the essential use allocations because the total amount of EUAs allocated for use in the NDA holder's MDI products (*i.e.* the MDIs to be produced by the NDA holder themselves plus the MDI to be produced by contract filler) remains unchanged. Further, EPA is implementing provisions to allow transfer of EUAs between MDI companies. This provision, finalized in today's action, would allow this transfer to occur even in the absence of EPA re-apportioning the EUAs among these two companies.

One company requested additional volumes of CFCs beyond the amount allocated to them in the NPRM. This company stated that it had anticipated an earlier timing for launch of certain new products, and that their current supplier of pharmaceutical-grade CFCs may shut down production in the next few years. For these reasons, they requested additional EUAs for calendar year 2001 to continue MDI production without utilizing their strategic reserves.

EPA and FDA have concluded that the year 2001 essential use allocations already reflect the contingencies raised by the commenter and are protective of public health. These allocations are calculated to insure that the full range of medical needs is met throughout the entire patient population. It should be noted that this company, as well as all essential use holders, now have the opportunity to obtain additional EUAs through trading, and also had the opportunity to request additional CFCs for the year 2002 in response to the notice requesting essential applications for the years 2002 and 2003 published November 1, 2000 (65 FR 65311).

Were There Other Comments Regarding the Allocation of CFCs for Use in MDIs?

One commenter who is a generic producer of MDIs stated that they were pleased with their proposed allocation. However, they commented that had they not been allocated EUAs, or had received an extremely low allocation, opportunities due to unexpected shifts in the market would fall to foreign manufacturers of MDIs who, the commenter asserts, can export CFC MDIs to the U.S. and are not subject to the same allocation requirements as U.S. MDI producers. EPA notes that companies who produce MDIs in other countries are also subject to the terms of the Montreal Protocol and must receive an allocation for CFCs to produce ''essential'' MDIs [5]. The major production of MDIs abroad is in Europe where each company's CFC requirements are also extensively reviewed before allocation.

What Was EPA's Method for Allocating Methyl Chloroform (MCF) for Use in Solid Rocket Motors?

With this action, EPA is allocating 60.1 metric tons of MCF for use in solid rocket motors, the same amount allocated in the years 1999 and 2000. EPA proposed to allocate MCF in an amount lower than would be consistent with Decision X/6 taken at the Tenth meeting of the Parties to the Protocol because we believed, based on knowledge of past MCF use, that allocating a larger amount would be unnecessary. EPA did not receive any comments on this issue, and is allocating 60.1 metric tons MCF as proposed in the NPRM.

[5] EPA believes that all countries that produce MDIs are parties to the Montreal Protocol.

When Is This Rule Effective?

This final rule is effective on January 8, 2001. Section 553(d) of the APA generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. However, APA section 553(d) excepts from this provision any action that grants or recognizes an exemption or relieves a restriction. Since today's action grants an exemption to the phase-out of production and consumption of CFCs, EPA is making this action effective immediately to ensure the availability of CFCs for medical devices during calendar year 2001.

Why is EPA Allocating CFC–11, CFC–12, and CFC–114 in the Aggregate To Each Company?

As discussed in the proposal, EPA is allocating essential use allowances for CFC–11, CFC–12, and CFC–114 in the aggregate in accordance with Decision X/6 of the Parties to the Montreal Protocol which states that ''the quantities approved under paragraph 2 above and all future approvals are for total CFC volumes with flexibility between CFCs within each group.'' Allocating CFCs for MDI in the aggregate instead of on a compound-by-compound basis provides MDI producers with flexibility in obtaining CFCs without causing additional damage to the stratospheric ozone layer since CFC–11, CFC–12 and CFC–114 all have the same ozone depleting potential of 1.0.

Timing of This and Future Essential Use Allocation Rules

One commenter noted that even though EPA sent letters to MDI companies in May 2000 requesting data needed to determine 2001 EUAs, the proposed allocation was not published until October. This commenter requested that EPA make every effort to issue a proposed rule allocating EUAs for 2002 in September of 2001, and states that as pharmaceutical-grade CFC production becomes increasingly tenuous, CFC suppliers are requiring advanced notice of MDI companies' CFC production needs. Further, MDI companies are unable to provide suppliers with this information until final EUA allocations are issued. Earlier rulemakings would help to ensure that MDI manufacturers are able to place CFC production orders, arrange for shipping, and make other administrative arrangements in a timely manner. EPA will make every effort to issue the notice of proposed rulemaking allocating essential use allowances for 2002 by September of 2001.

Another commenter requested that EPA issue the final CFC allocations for 2001 as soon as possible so that necessary CFCs may be ordered and delivered from the supplier in Europe in time to meet MDI production needs in 2001. EPA has expedited this final rule and believes that companies should have sufficient time to place their orders for CFCs for the coming year.

What Reporting Requirements Must I Adhere To When Using My Essential Use Allocation?

Any person obtaining class I controlled substances after the phase-out under the essential use exemptions in today's action is subject to all the restrictions and requirements in other sections of 40 CFR part 82, subpart A. Holders of essential use allowances or persons obtaining class I controlled substances under the essential use exemptions must comply with the recordkeeping and reporting requirements in 40 CFR 82.13. Instructions and forms for reporting are found in the Guidance Document for the Stratospheric Ozone Protection Program after January 1, 1996. This document can be obtained by contacting the Stratospheric Ozone Protection Hotline at (800) 296–1996 between 10:00 am and 4:00 pm Eastern Standard Time.

Under 40 CFR 82.3 and 82.4 (63 FR 41626, August 4, 1998), entities receiving essential use allowances must be the importer of record for quantities of CFCs brought into the United States. This requires that the essential use allowance holder be listed as the importer of record on Customs Form 7501. As a result, the essential use allowance holder who imports quantities of class I controlled substances is responsible for submitting both an Importer Quarterly Report and an Essential Use Holder Quarterly Report.

IV. Transfer of EUAs for CFCs Among Essential Use Allowance Holders

With this action EPA is adding essential use allowances to the list of allowances that can be transferred under 40 CFR 82.12. This change will enable companies to transfer EUAs for CFCs to other essential use holders for the production of MDIs. EPA believes that allowing EUAs to be transferred among essential use allowance holders will allow MDI companies to obtain CFCs beyond their allocation without increasing the total amount of ODSs allocated. EPA received three comments in support of the provision to allow transfer of EUAs among essential use holders. These commenters stated that this provision provides a responsible mechanism for addressing the inherent problem in attempting to predict the needs for MDI manufacturers.

One commenter requested a clarification of the proposed regulations regarding the use of a contract filler. The commenter took issue with the fact that EPA would have to approve the use of a contract filler. The commenter believes it should be at the company's discretion as to whether it produces the product in-house or through the use of a contract filler. The new regulations provide a mechanism for transfer of EUAs from an NDA holder to a contract filler (provided they already have EUAs). However, EPA must continue to exercise strict control over the amount of CFCs produced and or imported to ensure U.S. compliance with the Decisions of the Parties to the Protocol. Thus, EPA believes that it is necessary to approve the transfer of EUAs between an NDA holder and a contract filler. It should be noted that EPA is not approving or disapproving the use of a contract filler per se, but merely ensuring that the ''transferor'' has sufficient allowances to cover the transaction.

Under the New Regulations Can I Transfer EUAs for CFCs To Anyone I Want?

No; EUAs for CFCs are only transferable among those companies that have applied for and received EUAs for the year 2001. In addition, companies must certify in writing to EPA that the EUAs will only be used in the production of essential medical devices as defined in the FDCA at 21 CFR 2.125 and considered essential by the Parties to the Protocol.

Can EUAs for CFCs Be Transferred From Year to Year?

No; EUAs are not transferable from year to year. Any EUAs for CFCs not expended in 2001 will expire at the end of 2001.

Is There a Cost for Transferring EUAs?

Yes; the CAA at section 607(a) states that rules governing transfer of allowances for the production of class I and class II substances ''* * * shall insure that the transactions under the authority of this section will result in greater total reductions in the production in each year of class I and class II substances than would occur in that year in the absence of such transactions.'' In compliance with this section, current regulations at 40 CFR 82.12 governing transfers of production and consumption allowances require one percent of the traded amount to be deducted from the transferor's

unexpended allowances. EPA proposed to amend the regulations so that in the case of EUA transfers, one tenth of one percent of the amount traded would be deducted from the transferor's account. As stated in the preamble to the proposed rule, EPA believes that given the relatively small amount of EUAs available for use in MDIs, and that providing sufficient EUAs for MDIs is critically important for protecting public health, deducting one percent of the amount of EUAs to be traded would be too high a penalty and may create a barrier against transferring EUAs freely. Reducing the amount deducted from the transferor's account overcomes this potential barrier. EPA received no adverse comments on this issue, and is amending the regulation as described above.

How Can I Transfer EUAs From My Company to Another?

In order to complete a transfer of EUAs for CFCs from one essential use allowance holder to another, the transferor would have to submit to the Administrator a letter with the information requested in 40 CFR 82.12(a)(1). Under the regulations at 40 CFR 82.12, the transferor must submit to the Administrator a transfer claim with the following information:

1. The identities and addresses of the transferor and transferee.
2. The names and telephone numbers of contact persons for both the transferor and transferee.
3. The type of allowances being transferred, which in this case would always be essential use allowances.
4. The group of controlled substances being transferred, which would always be Group I.
5. The amount of allowances being transferred in kilograms.
6. The calendar year for which the allowances are being transferred (*e.g.* calendar year 2001).
7. The amount of unexpended essential use allowances for the current calendar year.
8. The amount of the 0.1% offset applied to the unweighted amount traded that will be deducted from the transferor's allowance balance.

A sample form that outlines the necessary information that a transferor must submit to EPA will be available through the Stratospheric Ozone Hotline at 1–800–296–1996.

As specified in 40 CFR 82.12, EPA will determine, based on records maintained by the EPA ODS tracking system, whether the transferor possesses as of the date of the transfer claim, unexpended allowances sufficient to cover the transfer claim (*i.e.,* the amount to be transferred plus one tenth of one percent of that amount). Within three working days of receiving a complete transfer claim, EPA will notify the transferor and transferee if the transferor has sufficient unexpended allowances to confer the transfer claim, and will issue a notice indicating that EPA does not object to the transfer. EPA will then reduce the transferor's balance of essential use allowances by the amount to be transferred plus one tenth of one percent of that amount. When EPA issues a no objection notice, the transferor and the transferee may proceed with the transfer.

If EPA's records show that the transferor has insufficient unexpended allowances to cover the transfer claim, or that the transferor has failed to respond to one or more Agency requests to supply information needed to make a determination, EPA will issue a notice disallowing the transfer. Within 10 working days after receipt of notifications, either party may file a notice of appeal, with supporting reasons, to EPA, in which case EPA may either affirm or vacate the disallowance. If no appeal is taken by the tenth working day after notification, the disallowance shall be final on that day. (The transferor and transferee will be held liable in accordance with section 113 of the Act for any violations that occur as a result of an improper transfer.) In the event that EPA does not respond to a transfer claim within three working days of receipt of the completed claim, the transferor and transferee may proceed with the transfer and EPA will reduce the transferor's balance accordingly.

V. Administrative Requirements

A. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector.

Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Section 204 of the UMRA requires the Agency to develop a process to allow elected state, local, and tribal government officials to provide input in the development of any proposal containing a significant Federal intergovernmental mandate.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, or tribal governments or the private sector. Because this rule imposes no enforceable duty on any State, local or tribal government it is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments; therefore, EPA is not required to develop a plan with regard to small governments under section 203. Finally, because this rule does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected state, local, and tribal officials under section 204.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is Significant and therefore subject to OMB review and the requirements of the Executive Order. The Order defines Significant regulatory action as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy,

productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined by OMB and EPA that this action is not a Significant regulatory action under the terms of Executive Order 12866 and is therefore not subject to OMB review under the Executive Order.

C. Paperwork Reduction Act

This action does not impose any new information collection burden as defined by the Paperwork Reduction Act (PRA). The Office of Management and Budget's draft guidance on PRA states that a rule is exempt from OMB review if it ''explicitly applies to nine or fewer persons''. Since the reporting requirements in this rule are not of general applicability, and apply only to the eight entities receiving EUAs for CFCs, and only if a company decides to transfer EUAs to another essential use holder, we believe that this rule is exempt from the requirement of submitting an Information Collection Request and undergoing OMB review.

However, OMB has previously approved the information collection requirements that are contained in the existing regulations at 40 CFR 82.12 that set forth the process for inter-company transfers of consumption allowances under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0170 (EPA ICR No.1432.17). Copies of the ICR document(s) may be obtained from Sandy Farmer, by mail at the Office of Environmental Information, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at farmer.sandy@epa.gov, or by calling (202) 260–2740. A copy may also be downloaded off the internet at http://www.epa.gov/icr. Include the ICR and/or OMB number in any correspondence.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

D. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility

After considering the economic impacts of today's proposed rule on small entities, EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this rule. EPA has also determined that this action will not have a significant economic impact on a substantial number of small entities. This rule does not have a significant impact on a substantial number of small entities. There are only ten entities that are affected by this rulemaking (see table I above). This rule does not have an adverse economic impact on any entity because it grants exceptions to a pre-existing ban.

F. Applicability of Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it implements the phase-out schedule and exemptions established by Congress in title VI of the Clean Air Act.

G. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in this regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This final rule does not involve technical standards. Therefore, EPA did not

consider the use of any voluntary consensus standards.

H. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 432255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide the Office of Management and Budget, in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner. This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule will affect only the ability of private entities and the national government to request production of controlled ozone-depleting substances. Thus, the requirements of section 6 of the Executive Order to not apply to this rule.

VI. Judicial Review

Under section 307(b)(1) of the Act, EPA finds that these regulations are of national applicability. Accordingly, judicial review of the action is available only by the filing of a petition for review in the United States Court of Appeals for the District of Columbia Circuit within sixty days of publication of the action in the **Federal Register**. Under section 307(b)(2), the requirements of this rule may not be challenged later in the judicial proceedings brought to enforce those requirements.

VII. Submittal to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Therefore, EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective January 8, 2001.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Exports, Imports, Reporting and recordkeeping requirements.

Dated: December 28, 2000.

Carol M. Browner,

Administrator.

40 CFR Part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.4 is amended by revising the table in paragraph (t)(2) to read as follows:

§ 82.4 Prohibitions.

* * * * *

(t) * * *

(2) * * *

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2001

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease (in metric tons)		
Medeva Americas, Inc.	CFC–11 or CFC–12 or CFC–114	189.00
Boehringer Ingelheim	CFC–11 or CFC–12 or CFC–114	338.36
Glaxo Wellcome	CFC–11 or CFC–12 or CFC–114	858.10
Aventis	CFC–11 or CFC–12 or CFC–114	190.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	304.51
Sidmak Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	192.20
Schering Corporation	CFC–11 or CFC–12 or CFC–114	1025.20
Sciarra Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	1.3
(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	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

* * * * *

3. Section 82.12 is amended by revising paragraphs (a)(1) introductory text, (a)(1)(i)(H), (a)(1)(ii) introductory text, (a)(1)(ii)(A), and (a)(1)(iii) to read as follows:

§ 82.12 Transfers.

(a) * * *

(1) Until January 1, 1996, for all class I controlled substances, except for Group VI, and until January 1, 2001, for Group VI, any person (''transferor'') may transfer to any other person (''transferee'') any amount of the transferor's consumption allowances or production allowances, and effective January 1, 1995, for all class I controlled substances any person (''transferor'') may transfer to any other person (''transferee'') any amount of the transferor's Article 5 allowances, and after January 1, 2001 any essential use allowance holder (''transferor'') may transfer essential use allowances for CFCs to any other essential use allowance holder for CFCs (''transferee'') solely for the production of essential products (defined at 21 CFR 2.125) as follows:

(i) * * *

(H) The amount of the one percent offset applied to the unweighted amount traded that will be deducted from the transferor's production or consumption allowance balance (except for trades from transformers and destroyers to producers or importers for the purpose of allowance reimbursement). In the case of transferring essential use allowances, the amount of one tenth of one percent of the amount traded will be deducted from the transferor's allowance balance.

(ii) The Administrator will determine whether the records maintained by EPA, taking into account any previous transfers and any production, allowable imports and exports of controlled substances reported by the transferor, indicate that the transferor possesses, as of the date the transfer claim is processed, unexpended allowances sufficient to cover the transfer claim (*i.e.,* the amount to be transferred plus, in the case of transferors of essential use allowances, one tenth of one percent of the transferred amount, and in the case of transferors of production or consumption allowances, one percent of the transferred amount). Within three working days of receiving a complete transfer claim, the Administrator will take action to notify the transferor and transferee as follows:

(A) If EPA's records show that the transferor has sufficient unexpended allowances to cover the transfer claim, the Administrator will issue a notice indicating that EPA does not object to the transfer and will reduce the transferor's balance of unexpended allowances by the amount to be transferred plus, in the case of transfers of production or consumption allowances, one percent of that amount, or in the case of transfers of essential use allowances, one tenth of one percent of that amount. When EPA issues a no objection notice, the transferor and the transferee may proceed with the transfer. However, if EPA ultimately finds that the transferor did not have sufficient unexpended allowances to cover the claim, the transferor and transferee will be held liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper transfer.

* * * * *

(iii) In the event that the Administrator does not respond to a transfer claim within the three working days specified in paragraph (a)(1)(ii) of this section, the transferor and transferee may proceed with the transfer. EPA will reduce the transferor's balance of unexpended allowances by the amount to be transferred plus, in the case of transfers of production or consumption allowances, one percent of that amount, and in the case of essential use allowances, one tenth of one percent of that amount. However if EPA ultimately finds that the transferor did not have sufficient unexpended allowances to cover the claim, the transferor and transferee will be held liable for any violations of the regulations of this subpart that occur as a result of, or in conjunction with, the improper transfer.

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[FR Doc. 01–463 Filed 1–5–01; 8:45 am]

BILLING CODE 6560–50–U