International Pharmaceutical Aerosol Consortium

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Via electronic submission to
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Comments on
Docket Number EPA-HQ-OAR-2021-0044; FRL-10023-08-OAR
Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act

Dear Mr. Chang,

On May 19, 2021, the Environmental Protection Agency (EPA) published the proposed rule, "Phasedown of Hydrofluorocarbons: Establishing the Allowance Allocation and Trading Program Under the American Innovation and Manufacturing Act,"[1] to implement certain provisions of the American Innovation and Manufacturing Act of 2020 ("the AIM Act"). EPA's proposed rule would establish a framework to phase down the production and consumption of listed hydrofluorocarbons (HFCs) through an allowance allocation and trading program.

The International Pharmaceutical Aerosol Consortium (IPAC)[2] appreciates the opportunity to submit these comments on the proposed rule. In the United States, IPAC worked very closely with EPA and the Food and Drug Administration (FDA) on the essential use process under the US Clean Air Act and has a depth of experience on issues relevant to the provisions of the rulemaking relevant to HFCs as a propellant for pressurized metered dose inhalers (MDIs). MDIs are one of six applications specified in the AIM Act for which EPA "***shall allocate*** the ***full quantity*** of allowances necessary based on projected, current, and historical trends." (See (e)(4)(B)(iv) of the AIM Act, emphasis added). IPAC understands that the legislative intent of this provision was to ensure that adequate supplies of HFCs remain available to meet patient need for MDIs and to avoid any disruptions in the supply chain. With this important patient care objective in mind,

[1] 86 Fed. Reg. 27,150 (May 19, 2021)

[2] IPAC was formed in 1989 in response to the mandates of the Montreal Protocol and fully supported a timely and effective transition away from chlorofluorocarbons (CFCs) under the Montreal Protocol that balanced patient health and environmental concerns. IPAC's mission is to ensure that environmental policies relevant to inhaled therapies are patient-centric and appropriately balance both patient care and sustainability objectives. HFC pressurized metered dose inhalers (MDIs) played a critical role to the transition as one of the key ozone-friendly alternatives developed to replace CFC MDIs. IPAC's members: AstraZeneca, Boehringer Ingelheim, Chiesi, GSK, Kindeva, Organon, and Teva.

IPAC's comments are focused on the elements of the proposed rule related to determining the application-specific allowances for MDIs. We also note that in light of antitrust/competition laws and commercial sensitivities and under the short timeframes, IPAC did not have access to detailed data and information relevant to the Notice of Data Availability (NODA) and MDI Market Characterization report. Therefore, we encourage EPA to consult fully and carefully with all entities that could be impacted by the proposed rule, including propellant suppliers, MDI manufacturers, MDI importers, and others. This is likely to be the most efficient and productive approach. IPAC applauds EPA for their energy and proactive engagement with IPAC and the MDI sector to understand the market, clarify data needs, and ensure companies are well informed of the opportunity to provide feedback in this important rulemaking. IPAC has supported EPA's efforts by informing MDI manufacturers that are not members of IPAC of the rulemaking and opportunity to provide comments and information.

The provisions of the proposed rule limiting transfer outside the MDI sector and the reporting requirements will allow EPA to closely track consumption in the MDI sector and enhance understanding of the needs of the sector consistent with the overall environmental objectives of the AIM Act. It is important to remember that the HFC volumes currently needed to meet demand for MDIs (which IPAC estimates to be 1,200 to 1,500 metric tons total, annually) represent a very small proportion of the overall volume of HFCs to be used in all sectors.

Topics Specific to MDIs

- EPA is proposing to define MDIs as "a handheld pressurized inhalation system that delivers small, precisely measured therapeutic doses of medication directly to the airways of a patient. MDIs treat health conditions such as asthma and chronic obstructive pulmonary disease and are approved for such use by the U.S. Food and Drug Administration (FDA)." (86 Fed. Reg. 27208). IPAC supports this definition.
- IPAC encourages EPA to refine its estimate of HFCs in MDIs for accuracy. In the proposed rule, EPA states: "EPA estimates that in 2020, approximately 458 MT of HFC-134a and 78 MT of HFC-227ea propellant were contained in MDIs sold in the US. EPA received comments to the market characterization released with the NODA stating that the demand was twice what EPA estimates." IPAC believes that the comments to the NODA more accurately describe the market and we currently estimate that it is between 1,200 to 1,500 metric tons. This estimate is based upon our understanding of the MDI market, data shared by suppliers, historical CFC usage, and IPAC member feedback. In our response to the NODA, IPAC raised questions regarding the data sources and assumptions set forth in the market characterization (which we understand was developed on very short notice with limited data from industry). IPAC urged EPA to consult with propellant suppliers regarding estimated HFCs used given that the market for medical propellant is small and reasonably straightforward to segregate from other end uses due to the stringent purity requirements and specialized nature of the market.
- In the proposed rule, EPA anticipates the continued use of HFCs in MDIs: "[t]he use of HFC MDIs in the United States, absent a transition to alternatives, is expected to continue as

they may be more appropriate for certain patients than NIK medical inhalers, such as when the patient requires a reliever medication for exacerbations of asthma or other requirements (e.g., inhalation strength)." IPAC concurs with this statement. Additionally, it should be noted that future therapies may benefit from the delivery of medications to the lungs by MDIs beyond asthma and COPD. IPAC supports access to HFC propellants for MDIs in development in order to meet patient need for both current and future therapies. IPAC understands that EPA is not accepting comments on potential transitions to next generation technologies in the current rulemaking. IPAC would be pleased to provide further information on alternative MDI propellants in future rulemaking proceedings.

Timing of Issuance of Allowances

- EPA plans to issue allowances for 2022 by 1 October 2021. EPA notes that they have "focused on what can be implemented in a short timeframe" and that they will seek additional input in future years in order to allow more time for consideration of issues and to learn from experience. IPAC supports this approach. In future years, it may be prudent and efficient to issue multi-year application-specific allowances. However, in this initial year and given the extremely tight timeframes imposed by the AIM Act, IPAC agrees that undertaking an annual process for application-specific allowances for MDIs at least for 2022 and 2023 makes sense and we will all learn from the experience[3]. We also understand the need to accurately determine the amount of the application-specific allowances which must be provided for under the general cap of available allowances. This is another supporting rationale for undertaking an annual approach to issuing allowances for at least two years.

Application-Specific Allowances – Criteria for Evaluation and Issuance of Allowances (Section 84.13)

- IPAC supports creating a category of allowances that would be issued only to entities in the six listed applications in the AIM Act, including MDIs.
- EPA proposes that allowances issued under the AIM Act be an exchange value-weighted number, rather than having allowances that are specific to each HFC. IPAC believes that this is reasonable and prudent for the reasons outlined by EPA and supports this approach.
- EPA proposes to determine the quantity of application-specific allowances to each company by taking the greater of the regulated substances used by the company in the prior year multiplied by:
    - the average growth rate of use by the company over the past three years; or
    - the average growth rate of use by all companies requesting allowances for that specific application over the past three years.

[3] We understand that other sectors may prefer to have allowances issued for multiyear periods (e.g., 2022-2023) and for allowances for sectors ***other than MDIs*** we would support that approach if it is pragmatic and feasible to predict needs based upon available data.

IPAC generally supports this approach with the important additional feedback that EPA should have the flexibility to consider additional factors, including patient need for MDIs (see below). IPAC supports the allowances being allocated to individual MDI companies with the understanding that they can transfer to propellant suppliers seamlessly (with no offset reduction) if, for example, it is necessary because they are the importer of record of the bulk HFCs (see Section 84.13 (h): *"conferring application-specific allowances to a producer or importer is not subject to the offset required of transfers of allowances described in § 84.19"*).

- EPA also seeks comment on "whether EPA should allow for consideration of individual circumstances factually documented to the Agency (e.g., when a company projects significant growth due to acquiring another company)." IPAC strongly urges EPA to allow for consideration of individual circumstances of companies as well as the flexibility to consider any factor relevant to ensuring that sufficient supply of HFCs is available to meet patient need. Some examples that would have implications for the number of allowances needed include:
    - Approval of a new medicine delivered via MDI that addresses an unmet patient need. This would likely result in an increased need of current HFCs for at least some period.
    - Public health emergencies (e.g., COVID-19 pandemic) that may increase demand for certain MDIs.
    - An increase in HFCs if a company needs to manufacture additional MDIs to avoid supply chain disruption following the unlikely incidence of a quality issue in light of FDA's stringent quality specifications.
    - Changes in corporate structure, such as mergers, acquisitions, changes in parent companies and spinoffs.
    - A company's sale or acquisition of MDIs from an unaffiliated company.

  Allowing for consideration of facts and circumstances provides the flexibility for EPA to respond to unexpected scenarios that are difficult to predict in advance. IPAC encourages EPA to continue seeking feedback from stakeholders, including pharmacies, clinicians, hospital associations, patient associations, industry associations such as IPAC, and others with knowledge about the respiratory healthcare ecosystem. A core reason that the essential use process for CFCs in the United States was successful was the open and constructive collaboration among stakeholders. If helpful, IPAC would be pleased to facilitate a stakeholder group that could meet periodically and share information similar to the US Stakeholders Group on MDI Transition.
- EPA seeks comment on whether gross domestic product (GDP) or U.S. population growth rates would be appropriate for the MDI application. IPAC has undertaken an initial review of both metrics and believes that neither is appropriate in this context. Rather, we urge a patient-focused approach which would seek to understand what volume of HFCs is necessary to meet patient need. GDP is unlikely to be a useful proxy for the prevalence of respiratory illnesses and other factors relevant to ensuring patient access to necessary

medicines. Given the unique aspects of the market, we believe MDI manufacturers are best suited to provide data on HFC need for MDIs. In addition, FDA, patient, and clinician groups (*e.g.*, American Lung Association, COPD Foundation, and the American Thoracic Society) may be helpful resources. Equally well, population growth does not necessarily provide insight into the prevalence of respiratory illnesses or other diseases that could require the use of MDIs. A combination of market growth rates (as outlined above) and the particular circumstances of a company would provide a much more useful and accurate metric for assessing the allowance for MDIs.

- Application-specific allowances seem to only be required for acquiring bulk HFCs produced in the US or bulk HFCs imported into the US. An allowance would not be required for import of finished product although EPA is seeking feedback on this point. IPAC understands this is a complex, multifaceted issue. Given the short timeframe for comment, we do not have a detailed position on these issues but would support further dialogue on a data reporting process that would allow the EPA to monitor import of HFC finished products in support of any future regulatory actions that may be needed to meet environmental objectives.

Transfer Provisions for Application-Specific Allowances (Section 84.21)

We note that the transfer provisions outlined in the proposal are largely based upon the transfer process that was applicable to CFCs and other ozone depleting substances (ODS). Based upon IPAC's prior experience this seems a reasonable approach. IPAC concurs that transfers of application-specific allowances should be limited to within the application-specific allowance. IPAC urges EPA to consider whether the offset provision should apply to application-specific allowances for the MDI sector given the critical patient need.

Reporting Requirements (Section 84.31)

- IPAC concurs with the proposal that producers keep records to distinguish between HFCs produced with application-specific allowances and those produced with general pool production.
- EPA proposes that holders of application specific allowances must certify to producers and importers when purchasing HFCs using allowances that they were purchased for the specific use. IPAC concurs with this approach.

Set Aside Pool of Allowances (Section 84.15)

IPAC supports the set aside pool of allowances. This will help ensure that new entrants to the MDI market, or parties that did not have notice of the rulemaking, will have access to allowances to meet patient need.

Auditing of Recordkeeping and Reporting (Section 84.33)

The auditing requirements are very specific and may be burdensome and challenging for companies. Undertaking auditing in the initial allowance allocation period would be extremely challenging from a timing perspective. IPAC believes that the reporting requirements under the

regime should provide appropriate accountability under the circumstances. The MDI sector is a tightly regulated and controlled market. We are not aware of any issues with illegal imports in MDIs.