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**VIA ELECTRONIC DELIVERY & FIRST-CLASS MAIL**

Yvette Lawrence  
Internal Revenue Service  
Room 6129  
1111 Constitution Avenue NW  
Washington, D.C. 20224

Re: Comments Regarding Special Rules for Certain Medical Uses of Chemicals that Deplete the Ozone Layer (26 C.F.R. §§ 52.4681, 52.4682)

Dear Ladies and Gentlemen:

Pursuant to Request for Comments contained in 79 F.R. 3922 issued January 23, 2014 (the "Notice"), alliantgroup, L.P. respectfully submits the following comment on the final ozone-depleting chemical ("ODC") regulations, particularly as they relate to metered-dose inhalers ("MDI"). We are grateful for the opportunity to comment on the regulations and welcome the chance to meet with representatives of the Service to discuss the following comments in greater detail or to answer any questions.

Background

In 1987, the United States and several other countries entered into the Montreal Protocol ("Protocol"). The purpose of the Protocol was to curb the worldwide production of ODCs and halt the deterioration of the Earth's ozone layer. Under the terms of the Protocol, developed countries would neither produce nor consume certain ODCs after 1995. The United States furthered the purpose of the Protocol by imposing the ODC tax, which is codified in 26 U.S.C. §§ 4681, 4682, and the regulations thereunder. *See House Committee Report for HR 101-247, P.L. 101-239 at Title XI, Subtitle E.* The tax is an excise tax imposed on chemicals that deplete the ozone layer. The tax was initially imposed in 1990 and its regulations were finalized in 1995.

Although the Protocol generally prohibits the production and consumption of ODCs, Decision IV/25 of the Protocol allows countries to produce and consume ODCs for an "essential use." Under the Protocol, an ODC use is essential if it is a medical or safety necessity and no environmentally friendly alternative is widely available. The Food and Drug Administration ("FDA"), in consultation with the Environmental Protection Agency ("EPA"), determines whether a given ODC qualifies for an essential use. Once a determination of essentiality has been made, the United States, through the EPA, applies to the parties to the Protocol for a production and consumption allowance for the essential use of a given ODC.

The United States had successfully applied for an essential use exemption for ODCs used as propellants in MDIs by the time that the final ODC tax regulations were issued in October 1995. This exemption was reflected in the final ODC tax regulations. Specifically, the regulations ensured a lower tax rate on ODCs used as propellants in MDIs after 1992 or sold in a qualifying sale after 1992. *See* Treas. Reg. § 52.4682-1(h); *see also* PL 102-486, 1992 HR 776, Sec. 1932(b) (specifying the reduced rate of tax, which is currently not reflected in the statute). The regulations further allowed for a credit or refund for taxes paid in excess of the taxes owed under the reduced rate for ODCs used in MDIs. *See* Treas. Reg. § 52.4682-1(h)(2). Finally, we should note that Congress amended the ODC statute in 1996 to exempt ODCs used as propellants in MDIs or sold in a qualified sale from the ODC tax altogether. *See* PL 104-188, 1996 HR 3448, Sec. 1803(b); *see also* I.R.C. § 4682(g)(1).

The final regulations also exempted ODCs sold in qualifying sales for use as propellants in MDIs from the Floor Stocks Tax. Treas. Reg. § 52.4682-4(b)(2)(vii). The Floor Stocks Tax is imposed on ODCs that are held for sale or use in further manufacture by a person other than the manufacturer or importer of the ODC on January 1<sup>st</sup> of a given year. Treas. Reg. § 52.4681-1(a)(3). The tax essentially captures the annual increase in the tax rate imposed on a given ODC.

In 2005, the FDA amended its rules to remove the essential use designation for MDIs using ODCs as of December 31<sup>st</sup>, 2008. The FDA explained that environmentally friendly inhalers, particularly inhalers using hydrofluoroalkanes (“HFA”), were sufficiently safe, effective and available to satisfy the health needs of individuals with asthma and related pulmonary problems. The deadline for phasing out these MDIs was first extended to December 2012 and finally to December 2013. The FDA has published a list of the 7 inhalers using ODCs that have been used in the U.S. along with their phase-out dates. As of December 31<sup>st</sup>, 2013, the sale of every inhaler on the list has been prohibited in the U.S.

Remove Reduced Rate of Tax Regulation and Exemption from Floor Stocks Tax for Chemicals Used in Metered-Dose Inhalers

The ODC tax was enacted to promote the goals of the Protocol, namely, to significantly decrease the worldwide production of ODCs. At the time of its adoption, the regulation imposing a reduced rate of tax on ODCs used in MDIs complemented the essential use provision of the Protocol. Specifically, the FDA had designated the use of ODCs in MDIs as essential and the EPA had secured this essential use status from the parties to the Protocol.

However, the FDA does not currently recognize MDIs using ODCs as essential and the United States has not secured essential use status for these inhalers. Not only does the FDA not currently recognize this designation, but it has banned the sale of all MDIs using ODCs in the United States.

Given these developments, the reduced rate of tax imposed on MDIs in the final regulations no longer complements the provisions of the Protocol, whose purpose the tax is intended to promote. As such, the regulation should be repealed. The same holds true for the provisions allowing for a credit or refund for excess taxes paid on ODCs used in MDIs as well as the exemption from the floor stocks tax.

It is important to note that we make these recommendations predicated upon the validity of the FDA’s finding that environmentally friendly MDIs are sufficiently safe, effective and available for those who need them.

Adopt Regulations Allowing Companies One Year Grace Period Before Excise Tax is Imposed on ODCs  
Used in MDIs

We believe that applying a full I.R.C. §§ 4681 & 4682 tax on companies holding ODCs used in MDIs without giving these companies time to come into compliance constitutes an unjust burden. Although the FDA initially announced plans to ban MDIs using ODCs in 2005, the actual date of the ban has constantly been in flux, with various groups lobbying against the ban and congressmen pushing for a repeal of the ban. Additionally, the final phase-out date for MDIs using ODCs was December 31<sup>st</sup>, 2013. Given the uncertainty as to whether the MDI ban would survive repeal campaigns and the recent final phase-out date, it is not unreasonable for companies to have not yet adjusted their inventories and business plans to eliminate MDIs using ODCs.

Therefore, we suggest that Treasury adopt regulations specifying that the ODC tax, including the floor stocks tax, be imposed on ODCs used in MDIs following a one year grace period. This provision ensures both that the ODC tax will eventually complement the terms of the Protocol while also alleviating a potentially sudden and significant burden on businesses.

Conclusion

We believe that amending the ODC regulations to eliminate the beneficial provisions for ODCs used in MDIs while providing a one year grace period will be beneficial to all parties, consistent with both current and prior statutes, and within the Service's regulatory authority. We appreciate the opportunity to comment on the Notice, and would welcome the opportunity to meet with the Treasury Department to discuss the comments in greater detail or to answer any questions that you may have. Please do not hesitate to contact us with any questions or for any additional information that you would find useful.

Respectfully submitted,



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