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March 31, 2025

Via Electronic Mail [illegible]

The Honorable Lee Zeldin
Administrator
U.S. Environmental Protection Agency
Mail Code: 1101A
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Presidential Exemption: *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 89 Fed. Reg. 24,090 (Apr. 5, 2024): ALCON Research Ltd., ALCON Advance Optic Device Center, North Facility, 2 Vision Lane, Lesage, Cabell County, West Virginia 25537

Dear Administrator Zeldin:

ALCON Research Ltd.'s ALCON Advance Optic Device Center, North Facility located at 2 Vision Lane, Lesage in Cabell County, West Virginia (AODC) respectfully requests a two-year Presidential Exemption from the *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review* regulation, published at 89 Fed. Reg. 24,090 (Apr. 5, 2024) (EtO NESHAP Rule).

The Emissions Standards or Limitations Subject to the Request:

National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, published at 89 Fed. Reg. 24,090 (Apr. 5, 2024), and 40 C.F.R. Part 63, Subpart O. The limitations that are the subject of this exemption request include the emission standards and emission capture requirements applicable to sterilization chamber vents, aeration room vents, Group 1 Room emissions, and Group 2 Room emissions, the Permanent Total Enclosure (PTE) requirements of EPA Method 204 of Appendix M, 40 C.F.R. Part 51, and the requirement to install and operate

Continuous Emission Monitors (CEMs) in accordance with the requirements of Performance Specification 19 in Appendix B and Procedure 7 in Appendix F to 40 C.F.R. Part 60, all as applied at AODC.

Exemption Period Request:

ALCON Research, Ltd., is requesting a two-year Presidential Exemption and extension of the applicable compliance deadlines of the *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review* regulation, published at 89 Fed. Reg. 24,090 (Apr. 5, 2024), as applied at AODC.

Background

Founded more than 75 years ago in Fort Worth, Texas, ALCON is the largest eye care company in the world. It is the global leader in eye care, dedicated to helping people ***See Brilliantly***. Today, more than one billion people live with some form of uncorrected visual impairment. The impact of these treatable problems is significant. We see a world where treatable, preventable eye health conditions receive the attention they need, regardless of an individual's geography, gender, age or socioeconomic status. Our Social Impact and Sustainability strategy is focused on three pillars Brilliant Lives, Brilliant Innovation and Brilliant Planet. The pillars include social impact and environmental goals that hold us accountable and measure progress. ALCON is dedicated to advancing a future where the opportunity to protect, restore or enhance vision is available to everyone, including our U.S. military and military veterans.

In 2024 alone, ALCON sold more than 52,000 vision correction lenses to the U.S. Department of Defense and other U.S. government entities through government contracts. Alcon's commitment to the United States and its local communities is illustrated by ALCON's Children Vision Program a program that works with local school districts to provide no-cost comprehensive exams and glasses for students. As part of this program, ALCON AODC provides free vision screenings for students in Cabell County, West Virginia, including 2,472 student screenings in 2024 alone.

The ALCON AODC North Facility is located on a 21-acre industrial park in a rural community, surrounded by industry, a sewer plant, and warehouses. It is located adjacent to what will become an ALCON warehouse at 1 Vision Lane which is located on a separate 26-acre parcel. The ALCON AODC North Facility manufactures Intraocular Lenses (IOLs) and IOL delivery devices. An IOL is a tiny, artificial lens for the eye, which replaces the eye's natural lens that is removed during cataract surgery. ALCON's IOL portfolio reflects a strong legacy of eye care innovation based on ALCON's significant strategic commitment to research and development.

Presidential Exemption Request

A. AODC's Current Sterilization Process Is Uniquely Designed to Minimize Ethylene Oxide Emissions

As surgical implantable devices, IOLs must be carefully sterilized. The ALCON AODC facility is an existing minor source facility which operates three (3) identical EtO sterilization chambers that are uniquely designed to minimize EtO emissions generated during the sterilization process. IOLs are sterilized in these chambers inside their primary Tyvek pouch packaging, using metal racks with three (3) plastic pallets per chamber. Unlike many EtO sterilization facilities, no cardboard or paper is used in AODC's sterilization process, which reduces residual EtO emissions after sterilization. Loading and unloading for each sterilization chamber is also automated, reducing potential employee exposure to EtO.

After sterilization, the IOLs (in their primary Tyvek pouch packaging) are transferred by enclosed mechanized conveyer into a 24-hour aeration chamber. The facility utilizes a Lesni Abatement Plant (water balancer and catalytic oxidizer) to treat the sterilization chamber vents (SCVs) and aeration room vents (ARVs). The facility has no chamber exhaust vents (CEVs). The aeration cells utilize exhaust air from the unloading area for makeup, and the aeration cell vents are routed to a low concentration inlet of the Lesni Abatement Plant. Both vent sources are routed through a single stack to the atmosphere.

After aeration, the IOLs are transported to a final Packaging and Labeling Area, where they are placed into cartons with tamper seals and placed in shipper boxes. Most commercial sterilizers sterilize products in their final packaging, which includes a lot of materials that will retain EtO and create longer aeration and/or more fugitive off-gassing downstream in trucks and distribution warehouses. AODC's sterilization process is uniquely designed to reduce aeration time and fugitive emissions in the off-gassing process thereby reducing emissions and risks to public health.

B. AODC's Current Ethylene Oxide Process Controls Are Already Highly Effective

At the present time, the ALCON AODC facility uses less than five tons of EtO on an annual basis. Moreover, the unique design of AODC's sterilization process is highly effective at reducing EtO emissions.

Total emissions from the AODC facility after existing controls already meet the requirements of the pre-2024 NESHAP regulations. Stack tests were conducted in 2019 by ALCON on the Lesni Abatement Plant stack and observed by the West Virginia Department of Environmental Protection, Division of Air Pollution Control. During the most recent testing, the Lesni Abatement Plant achieved an average destruction and removal efficiency (DRE) that exceeded 99.8%. Consequently, EtO stack emissions at AODC are extremely low. ALCON has been in

continuous compliance with the pre-2024 NESHAP regulations and has never been cited for violations of the applicable regulations.

AODC also engaged the leading provider of enhanced optical spectroscopy analytical solutions to conduct an Ethylene Oxide Workplace Exposure Site Evaluation between August 12 and September 6, 2024. The independent assessment company conducted continuous sampling at 17 locations throughout the facility over 26 days utilizing a Workplace Monitoring System (WMS). During the period of analysis, no position within the facility exceeded a 1ppm/8hr time-weighted-average (TWA) permissible exposure limit (PEL) under normal conditions. The largest 8hr TWA was 0.139 ppm. The same company noted in its final report that the EtO sampling recorded values at AODC were the **lowest** they had seen in any facility based on their extensive monitoring experience.

In addition, the EPA evaluated the cancer maximum individual risk (MIR) from ALCON's AODC facility in January 2024. *See Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2024 Risk and Technology Review Final Rule* at Table 2a-1. The facility-wide cancer MIR for AODC in the EPA's evaluation was very low at 0.2-in-1 million **far below** the 1-in-1 million cancer risk the EtO NESHAP Rule sets as a target.

C. Challenges Presented by the EtO NESHAP Rule

The April 5, 2024, EtO NESHAP Rule presents many technological, engineering and business challenges for ALCON. To comply with this revised rule, ALCON continues to research, design, plan, and consider: (1) product disruptions, (2) capacity reductions, (3) alternative compliance options such as off-shoring production, or out-sourcing sterilization, (4) development of new engineering design plans, and (5) vendors to provide the required PTE, CEMs, and new control systems.

The first three options for AODC compliance with the EtO NESHAP Rule product disruptions, capacity reductions, or off-shoring / out-sourcing production — are problematic for the domestic and national security reasons discussed below.

1. Limitation of Technology and Expertise

ALCON continues to research technologies and suppliers to achieve the applicable NESHAP requirements without negatively impacting its IOL manufacturing at the AODC facility. This research and review has included contacting engineering firms familiar with designing sterilization facilities and Method 204 compliant PTEs and reaching out to current abatement and EtO monitoring vendors, colleagues in the industry, and trade organizations.

As the April 5, 2024, EtO NESHAP Rule recognizes and acknowledges, there are limited vendors with the technology and expertise to plan, design, and install the PTEs, the air pollution controls, and the CEMs that are required by the 2024 EtO NESHAP Rule. *See* General Information at 89 Fed. Reg. 24090, 24102. ALCON has and continues to expend significant resources in an attempt to comply with the Rule. ALCON has held onsite meetings and demonstrations with several vendors of CEM equipment that advertise technology meeting the NESHAP requirements as well as experienced engineering design firms. ALCON has approved and expended significant Capital funding for a multi-disciplinary design firm to conduct the following for the AODC facility:

- An EPA Compliance Assessment to understand the NESHAP applicability to current operations and recommended options for compliance based on the facility's unique layout and challenges.

- An onsite 25-day EtO Monitoring Study using industry-approved cavity ring-down spectroscopy technology. This study was selected to better understand the fugitive emissions in Group 1 and Group 2 rooms as well as to afford the site with the opportunity to become familiar with the vendor and their equipment.

- A Basis of Design (BOD) study for the Method 204 PTE of Group 1 and Group 2 Rooms and the Dry Bed Abatement Facility required to support the PTE abatement exhaust.

- Develop a Rough Order of Magnitude (ROM) Budgetary Cost Estimate for the project.

2. Threat to Sterilization and Quality Control

Through this design process, ALCON has determined that compliance with the EtO NESHAP Rule threatens the integrity of AODC's sterilization and quality control process. Particulate (dust, hair, etc.) in the final packaging for an implantable medical device is a major risk. To minimize this risk, AODC maintains positive air pressure in its final Packaging and Labeling Area. However, this area is a Group 2 Room that would be required to be converted to a PTE under the revised EtO NESHAP Rule. Converting this area to a PTE would create a negative air flow into the Packaging and Labeling Area from surrounding rooms (including the facility's main hallway) and potentially contaminate the final packaging for the IOLs.

3. Inability to Meet Deadline Coupled with Uncertainty

Despite ALCON's extensive efforts to find cost-effective solutions to comply with the EtO NESHAP Rule, based on the studies and efforts provided above, the estimated cost for AODC to achieve compliance with the Rule at its current EtO usage is greater than 15% of ALCON AODC's annual operating budget, which is more than 50 times EPA's woefully underestimated cost of compliance for the facility. This exorbitant cost to achieve compliance is particularly

challenging given the controversy and litigation surrounding the new EtO NESHAP Rule. As EPA is aware, EPA announced on March 12, 2025, that it would reconsider the new EtO NESHAP Rule as part of a broader deregulatory initiative mandated under Executive Orders signed by President Donald Trump. The U.S. Court of Appeals for the District of Columbia has also scheduled oral arguments to hear from multiple parties challenging the EtO NESHAP Rule. The Executive Orders, the EPA deregulatory announcements, the ongoing EtO litigation, and the difficulties with timely obtaining an assured supply of technologies and expertise have created fundamental uncertainty as to the scope, timing, and content of compliance requirements. This creates significant uncertainty for companies like ALCON that would need to deploy significant resources to attempt to comply with the Rule without reducing or off-shoring production.

Moreover, and more importantly for its purposes, despite ALCON AODC's significant efforts to achieve compliance with the April 5, 2024, EtO NESHAP Rule requirements in a timely manner, ALCON is not able to identify and implement technology that will serve its unique needs by the compliance deadlines for the new EtO Rule. For the reasons discussed above (as well as others discussed below), ALCON's AODC facility requests a two-year exemption from the April 5, 2024, EtO NESHAP Rule, as provided for in Section 112(i)(4) of the Clean Air Act.

D. National Security Implications of Compliance with the EtO NESHAP Rule

As a global and world class leading producer of IOLs, it is extremely important that ALCON continue to produce high-quality cataract replacement lenses. Indeed, the ability of ALCON to produce IOLs is in the national security interests of the United States for several reasons. ALCON supplies 56% of the US IOL market and 32% of the global IOL market. Cataract surgery is one of the most frequently performed surgical procedures. According to the National Eye Institute, cataracts are the leading cause of blindness worldwide even though effective surgical treatment exists. Currently, surgical removal of the clouded lens followed by insertion of an IOL is the preferred treatment for cataracts. The clouded lens is usually removed through a process known as phacoemulsification. During phacoemulsification, an ophthalmic surgeon makes a small surgical incision in the cornea (approximately 2-3 millimeters wide) and inserts an ultrasonic probe that breaks up, or emulsifies, the clouded lens while a hollow needle removes the pieces of the lens. Once the clouded lens is removed, the surgeon inserts an IOL through the same surgical incision. An Advanced Technology IOL (ATIOL) is a type of IOL that also corrects for refractive errors, like presbyopia and astigmatism. ALCON's AODC facility in West Virginia reduces potential American dependency on imports of IOLs.

In addition to the eye care health crisis potentially associated with IOL product disruptions due to vendor delays, longer production times, packaging modifications, and/or production shutdowns for facility modifications, the United States global leadership in IOLs is a contributor to the economic stability of this country. It is important that the United States maintains its global leadership in R&D and in advanced manufacturing. ALCON is on the cutting edge of these initiatives in the eye care industry and maintaining and improving the U.S. eye care market

contributes to the economic stability of the United States. The economic stability of the United States is in the country's national security interests.

Beyond the economic stability justifications for ALCON's contributions to our nation's national security, ALCON also supplies U.S. military personnel and military veterans with cataract replacement lens. In 2024 alone, ALCON sold more than 52,000 vision correction lenses to the U.S. Department of Defense and other U.S. government entities through government contracts. The Defense Health Agency's Vision Center of Excellence (VCE) reports that military service members are more prone to traumatic eye injuries, with 68% occurring on the battlefield and 28% during noncombat work and training. These injuries, often blunt or penetrating, frequently require IOLs for sight-restoring cataract surgeries. In addition to supporting active duty members, the U.S. Department of Veteran Affairs commonly covers, provides, and performs cataract surgery for qualifying veterans. AODC should be permitted to continue manufacturing and sterilizing high-quality cataract replacement lenses for the U.S. military and military veterans.

Conclusion

Despite its significant efforts to achieve compliance with the April 5, 2024, EtO NESHAP Rule requirements in a timely manner, ALCON is not able to obtain and install the technology required by the new Rule by the compliance deadlines. Attempting to comply with the new Rule would result in several months of manufacturing shutdowns, product shortages, capacity reductions, and the need to explore out-sourcing sterilization of IOLs to reduce EtO usage. This would negatively impact national security by affecting U.S. military and veteran use of IOLs produced at the AODC facility, as well as the stability of U.S. markets, and potentially leave multiple millions of Americans in the general population dependent on imported IOLs for their sight. For these reasons, ALCON Research Ltd., requests a two-year exemption from the April 24, 2024, EtO NESHAP, as provided for in Section 112(i)(4) of the Clean Air Act.

In addition to the federal regulations, the April 5, 2024, EtO NESHAP has been adopted by reference at W. Va. Code R. § 45-34, as a federal counterpart regulation, in accordance with W. Va. Code § 22-5-4. Accordingly, ALCON requests that the two-year exemption equally apply to the West Virginia regulations.

Moreover, given the significant resource expenditure that will be required for AODC to attempt to comply with the Rule, the minimal environmental gain given the unique design of the AODC facility, and the potential impacts to AODC's quality control process, ALCON believes the EtO NESHAP Rule should be rescinded as applied to the AODC facility. ALCON also welcomes any future opportunity to provide EPA with the technical information it requires to promulgate a revised EtO NESHAP Rule that will not negatively impact critical medical devices manufactured and sterilized at the ALCON AODC facility.

Thank you for your consideration.

Sincerely,

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Submitted on behalf of ALCON Research Ltd., ALCON Advance Optic Device Center, North Facility, 2 Vision Lane, Lesage, Cabell County, West Virginia 25537

cc: Michael Egnor, Air Toxic Coordinator
West Virginia Department of Environmental Protection
(via electronic mail - Michael.Egnor@wv.gov and DEPAirQualityReports@wv.gov)