DATE: February 27, 2024

TO: Environmental Protection Agency (EPA)

THROUGH: Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB)

Office of the Executive Secretary, Department of Health and Human Services (HHS)

FROM: Food and Drug Administration (FDA)

SUBJECT: FDA Review of EPA Final Rule, "Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review"

FDA shares EPA's goal of improving public health by lowering exposure of sterilization facility workers and community members to ethylene oxide (EtO), while also maintaining the availability of sterile medical devices in the United States. We appreciated the opportunity to review and provide technical feedback through the Executive Order 12866 interagency review process on EPA's draft final rule regarding EtO emissions standards for sterilization facilities. As you know, FDA is responsible for overseeing the safety and effectiveness of medical devices, including sterile devices, and we collaborate with others to support the integrity of the medical device supply chain. Accordingly, we focused our feedback to EPA on aspects of the draft final rule that could lead to reductions in device sterilization capacity (either temporary or permanent) and, in turn, cause shortages that negatively impact patient access to sterile devices. EPA made changes to the draft final rule that, in combination with assurances regarding meaningful access to extensions or exemptions for the compliance deadlines, helps mitigate and manage potential risk of medical device shortages or other supply disruptions that could result from implementation of the final rule.

FDA provided comments through two rounds of review. On January 26, 2024, we provided initial feedback on EPA's first draft of the final rule, and we noted that the draft included key changes from the proposed rule to help mitigate impacts to the device supply chain. Further, we identified remaining aspects of the draft final rule that could result in either temporary or permanent reductions in device sterilization capacity, and we estimated the potential supply chain impact based on information in the draft final rule and draft regulatory impact analysis. We explained, for those reasons, we were unable to concur with the draft at that time.

On February 20, 2024, FDA concurred with comments on EPA's second draft of the rule. This draft reflected two important changes to reduce risk of negative supply chain impacts: 1) the continued waiver of the Title V permitting requirement, and 2) the addition of an option for facilities to demonstrate compliance with a site-wide emission reduction standard, as opposed to having to demonstrate compliance with each individual emission stream. Given these changes, FDA's prior estimates for reduced sterilization capacity would not apply to the second draft. The preamble helpfully included new language explaining

options for facilities to seek extensions of the compliance timelines if needed—*i.e.*, 1) the option under CAA section 112(i)(3)(B) and 40 CFR 63.6(i)(4)(i)(A) for States with delegated authority to grant an existing source an additional year to comply with section 112(d) standards, and 2) the option under CAA section 112(i)(4) for the President to exempt any stationary source from compliance for a period of not more than two years, and extend the exemption for one or more additional periods, each period not to exceed two years. Based on these changes, FDA concurred with comments on the rule.

Our remaining comments focused primarily on our recommendation that, to the extent possible, public clarity and regulatory certainty be provided about the options for facilities to secure compliance deadline extensions or exemptions, if needed, and EPA's plans for completing a separate action under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). From a supply chain perspective, it is crucial that facilities be able to obtain an extension or exemption, rather than reduce device sterilization capacity, if they are unable to comply by the statutory deadlines. The availability of extension and exemption options, such as the exemption under 112(i)(4), will be important to help mitigate any supply chain impacts that may occur.

On February 26, 2024, FDA reviewed the third draft of the final rule. The preamble helpfully included a new sentence regarding the FIFRA action, including that "OPP has been actively collaborating with the Office of Air and Radiation to ensure that the requirements of the FIFRA Interim Decision (ID) do not interfere with the requirements of this rule, and vice versa" and "OPP has been consulting regularly with other federal agencies and with industry trade groups, to discuss how best to harmonize the requirements of the FIFRA ID with the requirements of this rule, and to ensure that the operative standards, once finalized, will protect both workers and neighboring communities from the risks of EtO exposure while mitigating and managing any risk to the supply chain for sterile medical devices." With this change, FDA concurred on the final rule.

Again, FDA very much appreciated the opportunity to provide our perspective and work with EPA to help advance our shared public health goals.