FDA - Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding

The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention that today the Agency issued a guidance for immediate implementation for pharmacy compounders that experience shortages of the personal protective equipment (PPE) they typically use to compound human drugs that are intended or expected to be sterile. PPE shortages have the potential to significantly impact the quality, purity and availability of drugs that are compounded for patients, including those in critical need. The guidance discusses how pharmacies may be able to preserve PPE if supplies are limited.

Further, as a temporary measure to address the public health emergency posed by COVID-19, the agency is providing limited regulatory flexibility for compounders that cannot obtain sufficient supplies of PPE for sterile compounding, provided they adopt risk mitigation strategies as described in the guidance. FDA adopted this policy to help assure patient access to needed medicines and to reduce the risks of compounding when standard PPE are not available.

FDA wants to ensure that health care professionals are aware of this guidance and the potential for greater contamination risk when compounded drugs are prepared without standard PPE. FDA encourages health care professionals who purchase compounded drugs to engage with compounders to balance these risks and the need for compounded products for patient care.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at IGA@fda.hhs.gov.