The FDA Office of Intergovernmental Affairs would like to bring your attention to two updated guidances for the temporary compounding of certain human drugs during the COVID-19 public health emergency. Please contact IGA at IGA@fda.hhs.gov for further information. Thank you.

Updated Guidances for Compounding (503A & 503B) for Certain Drugs During COVID-19 PHE

Today, the FDA updated two guidances for the temporary compounding of certain human drugs during the COVID-19 public health emergency. These updates clarify certain policies to address urgent needs for hospitalized COVID-19 patients.

The guidance for temporary compounding of certain drugs by outsourcing facilities during the COVID-19 public health emergency has been updated to include timely product reporting by outsourcing facilities compounding drugs covered by the guidance. Hospitals can use this information, which FDA will post on its website, to help determine which outsourcing facilities are compounding drugs used for hospitalized patients with COVID-19. The guidance has also been updated to clarify polices for testing container-closures and product stability.

Additionally, the guidance has been updated to explain that, at this time, FDA does not intend to take action against an outsourcing facility for filling orders of a drug that is essentially a copy of an FDA-approved product, provided the drug was covered by this guidance within 90 days of the outsourcing facility compounding, distributing, or dispensing the drug.

The guidance for temporary compounding of certain drugs by pharmacy compounders during the COVID-19 public health emergency has been updated to include pharmacy compounder reporting to FDA on adverse events associated with drugs compounded under this guidance.

Hospitals that cannot obtain FDA-approved drugs and seek to use compounded drugs for their hospitalized patients should first contact outsourcing facilities that produce compounded drugs under more robust quality standards than those made by state-licensed pharmacies or federal facilities.

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