Dexamethasone Sodium Phosphate Added to the Lists of Drugs for Temporary Compounding by Outsourcing Facilities and Pharmacy Compounders

The FDA added dexamethasone sodium phosphate to the lists of drugs for temporary compounding by outsourcing facilities and pharmacy compounders during the COVID-19 public health emergency. These updates help address shortages and access concerns affecting some drugs urgently needed for hospitalized COVID-19 patients. The updated lists are referenced in the following guidances:

- Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency
- Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry

Hospitals that cannot obtain adequate supplies of FDA-approved drugs and are considering the use of compounded drugs for their hospitalized patients should first contact outsourcing facilities, which are subject to more robust quality standards than state-licensed pharmacies or federal facilities that do not register with FDA as outsourcing facilities.

The guidance for temporary compounding of certain drugs by outsourcing facilities during the COVID-19 public health emergency includes timely product reporting by outsourcing facilities compounding drugs covered by the guidance. Hospitals can use this information, which FDA posts on its website, to help determine which outsourcing facilities are compounding drugs used for hospitalized patients with COVID-19.

For more information, please visit FDA's Human Drug Compounding web site.