Fresenius Kabi – FDA authorizes foreign importation of cisplatin

- Cisplatin has been a shortage since February 2023 due to increased demand. To bolster supply, the Food and Drug Administration (FDA) is providing Fresenius Kabi with special authorization to temporarily import their cisplatin product, Kemoplat, into the U.S. This product is not a FDA-approved product but is being given special authorization due to the shortage.

- Cisplatin is an intravenous chemotherapy drug commonly used as part of a regimen to treat various cancers including testicular, ovarian, bladder, lung, cervical, and other cancers.

- At this time, no other entity except Fresenius Kabi is authorized by the FDA to import or distribute cisplatin in the U.S. and FDA has not announced plans to authorize any other products.

- Fresenius Kabi's imported cisplatin is available as a 50 mg/50 mL vial, the same concentration as other FDA-approved cisplatin products. The Fresenius Kabi cisplatin will have a unique NDC number (65219-359-50).

- In June 2023, the FDA granted special authorization to Qilu Pharmaceuticals based in China, to import cisplatin. As of September 18, 2023, the Qilu product is no longer available and all imported product has been distributed.

- Multiple manufacturers make cisplatin; some have product available, some are shipping in limited quantities during the shortage, and some have the drug on backorder. At this time, there is no information as to when the cisplatin shortage will resolve.