Subject:

FW: Pfizer Hospital Availability Update: Select Sterile Injectable Controlled Substance Products

Pfizer Inc. 275 North Field Drive Lake Forest, IL 60045



March 18, 2024

Availability Update for Select Sterile Injectable Controlled Substance Products

Dear Customer,

Pfizer is committed to providing timely supply information so that you can plan for patient care. As such, we want to notify you that we are anticipating additional supply interruptions and potential stock outs for select Pfizer Hospital Schedule-II controlled substance injectable products, outlined in the Appendix of this letter.

These anticipated additional supply interruptions have emerged due to recent changes described in the U.S Drug Enforcement Administration's (DEA) 2024 Annual Aggregate Quotas and Assessment of Annual Needs Final Order, which included regulatory changes in the administration of individual procurement quotas. These changes were implemented in January 2024 and have impacted Pfizer and our API suppliers' ability to secure necessary quotas to support historical production levels of our controlled substance sterile injectable products.

The U.S. Food and Drug Administration (FDA) and DEA have been notified, and Pfizer will continue to work collaboratively to address this challenge as soon as possible. To help ensure equitable distribution of inventory, we will release at historical demand levels to wholesalers and distributors, on a weekly basis, as possible, depending on inventory levels and Product Status.

Please recognize that this is a dynamic situation, and these Estimated Delivery Dates and Product Status may change, so we encourage you to check our <u>Availability Report</u>, updated weekly and accessible on the <u>PfizerHospitalUS.com</u> homepage, for the latest information. Pfizer will also continue to provide customers with timely updates on the availability of these products as needed.

For product availability questions, please reach out to your Pfizer Hospital sales representative or account executive. Alternatively, the Supply Continuity Team can be contacted between 7am and 5pm CT at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]).

Thank you,

Meera Bhavsar

Sterile Injectables Lead Pfizer Hospital U.S.

APPENDIX: Impacted Schedule-II Controlled Substance Injectable Products

Unit of Sale NDC	Product Description	Product Status (as of 3/13/24)	Estimated Next Delivery
00409-1176-30	Demerol™ (meperidine hydrochloride injection, USP) CII 25 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Supply Available	
00409-1362-01	Demerol™ (meperidine hydrochloride injection, USP) CII 25 mg/mL NexJect™ Single-dose Syringe Luer Lock (no needle)	Supply Available	
00409-1178-30	Demerol™ (meperidine hydrochloride injection, USP) CII 50 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Limited Supply	Nov-24
00409-1418-01	Demerol™ (meperidine hydrochloride injection, USP) CII 50 mg/mL NexJect™ Single-dose Syringe Luer Lock (no needle)	Depleted	Nov-24
00409-1179-30	Demerol™ (meperidine hydrochloride injection, USP) CII 75 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Supply Available	
00409-1180-69	Demerol™ (meperidine hydrochloride injection, USP) CII 100 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Limited Supply	Feb-25
00409-1181-30	Demerol™ (meperidine hydrochloride injection, USP) CII 1,500 mg/30 mL (50 mg/mL) Multiple Dose Glass Fliptop Vial	Supply Available	
00409-1805-01	Hydromorphone HCl Injection, USP CII 0.25 mg/0.5 mL NexJect™ Singledose syringe with luer lock (no needle)	Supply Available	
00409-4264-01	Hydromorphone HCl Injection, USP CII 0.5 mg/0.5 mL NexJect™ Singledose Syringe Luer Lock (no needle)	Limited Supply	Apr-24
00409-1283-31	Hydromorphone Hydrochloride Injection, USP, CII 1 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Limited Supply	Apr-24
00409-1283-37	Hydromorphone HCl Injection USP, CII 1 mg/mL NexJect™ Single Dose Syringe Luer Lock (no needle)	Supply Available	
00409-3365-10	Hydromorphone HCI Injection, USP, CII 2 mg/mL Single Dose Vial	Depleted	Nov-24
00409-1312-30	Hydromorphone Hydrochloride Injection, USP, CII 2 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Supply Available	
00409-1312-36	Hydromorphone HCl Injection USP, CII 2 mg/mL NexJect™ Single-dose Syringe Luer Lock (no needle)	Supply Available	
00409-1304-31	Hydromorphone Hydrochloride Injection, USP, CII 4 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Depleted	Apr-24
00409-2634-01	Hydromorphone Hydrochloride Injection, USP, CII (High-Potency Formulation) 10 mg/mL Single Dose Glass Fliptop Vial	Depleted	Nov-24
00409-2634-05	Hydromorphone Hydrochloride Injection, USP, CII (High-Potency Formulation) 50 mg/5 mL (10 mg/mL) Single Dose Glass Fliptop Vial	Depleted	Nov-24
00409-2634-50	Hydromorphone Hydrochloride Injection, USP, CII (High-Potency Formulation) 500 mg/50 mL (10 mg/mL) Single Dose Glass Fliptop Vial	Depleted	Nov-24
00409-1890-01	Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 2 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Supply Available	
00409-1890-23	Morphine Sulfate Injection USP, CII (Preservative Free) 2 mg/mL NexJect™ Single-dose Syringe Luer Lock (no needle)	Supply Available	
00409-1891-01	Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 4 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Supply Available	
00409-1891-23	Morphine Sulfate Injection USP, CII (Preservative Free) 4 mg/mL NexJect™ Single-dose Syringe Luer Lock (no needle)	Supply Available	

00409-1892-01	Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 8 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Supply Available	
00409-1893-01	Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 10 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle)	Supply Available	
00409-1893-23	Morphine Sulfate Injection USP, CII (Preservative Free) 10 mg/mL NexJect™ Single-dose Syringe Luer Lock (no needle)	Supply Available	
00409-3814-12	Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 5 mg/10 mL (0.5 mg/mL) Single Dose Glass Fliptop Vial	Limited Supply	Apr-24
00409-3815-12	Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 10 mg/10 mL (1 mg/mL) Single Dose Glass Fliptop Vial	Supply Available	
00409-1896-20	Morphine Sulfate Injection, USP, CII (Preservative Free) 1,000 mg/20 mL (50 mg/mL) Single Dose Vial	Depleted	Feb-25
00409-3382-21	Sufentanil Citrate Injection, USP, CII 50 mcg/mL Single Dose Glass Fliptop Vial	Depleted	Jun-24

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