

March 27, 2024

Controlled Substance Supply Update

To our valued customers,

We are aware that another supplier of injectable controlled substances may experience a supply interruption related to recent changes in the United States Drug Enforcement Administration's (DEA) active pharmaceutical ingredient (API) quota approval process.

As a leading manufacturer of sterile injectable medicines, Fresenius Kabi plays a critical role in ensuring hospitals have the medicines needed to treat patients. Currently we are in a position to assist with supply of select controlled substances. To maximize supply continuity, we will limit shipments of Dilaudid® (hydromorphone) Simplist® prefilled syringes and hydromorphone vials to 110% of historical levels (see **Table 1**) to approved wholesalers. At this time we will not accept direct orders. **Table 2**, below, lists other currently available Schedule-II controlled substances.

We continue to monitor demand and adjust production where appropriate. We will also prioritize production of low-dose Dilaudid (hydromorphone) Simplist prefilled syringes and hydromorphone vials. This approach maximizes units supplied to the market and helps reduce potential waste in clinical settings.

It is important to note that any significant surge in demand may impact our ability to maintain this assistance. All controlled substance manufacturers are affected by the change in the API quota request process. Our ability to react will be partially dependent on how quickly the DEA responds to requests for additional API.

Fresenius Kabi is committed to ensuring supply of critical drugs. We are communicating with the U.S. Food and Drug Administration and the U.S. Drug Enforcement Administration on this topic and will continue to work closely with these agencies to help prevent and mitigate supply interruptions.

For product availability updates, please see the [Product Availability Report](#) on our website, call our Customer Service team at 1-888-386-1300, or contact your wholesaler. For clinical questions, please contact Fresenius Kabi USA Medical Affairs at 1-800-551-7176, Monday - Friday between 8:00 a.m. and 5:00 p.m. (CST), or email: medinfo.USA@fresenius-kabi.com.

Thank you for your understanding and partnership as we manage this evolving situation.

Sincerely,



Pere Berkowitz
Vice President, Marketing

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Table 1. Fresenius Kabi Products Limited to Historical Usage

Product	Strength	Unit of Sale NDC
Dilaudid® (Hydromorphone Hydrochloride) Injection, USP CII Single Dose Simplist® Prefilled Syringe	0.2 mg per 1 mL	76045-121-11
Dilaudid® (Hydromorphone Hydrochloride) Injection, USP CII Single Dose Simplist® Prefilled Syringe	0.5 mg per 0.5 mL	76045-009-06
Dilaudid® (Hydromorphone Hydrochloride) Injection, USP CII Single Dose Simplist® Prefilled Syringe	1 mg per 1 mL	76045-009-11
Dilaudid® (Hydromorphone Hydrochloride) Injection, USP CII Single Dose Simplist® Prefilled Syringe	2 mg per 1 mL	76045-010-11
Hydromorphone Hydrochloride Injection, USP CII Single Dose Vial	1 mg per 1 mL	63323-852-25
Hydromorphone Hydrochloride Injection, USP CII Single Dose Vial	2 mg per 1 mL	63323-853-25
Hydromorphone Hydrochloride Injection, USP CII Single Dose Vial	4 mg per 1 mL	63323-854-10
Hydromorphone Hydrochloride Injection, USP High Potency Formula (HPF) CII Single Dose Amber Vial (HPF)	10 mg per 1 mL	63323-851-10
Hydromorphone Hydrochloride Injection, USP High Potency Formula (HPF) CII Single Dose Amber Vial (HPF)	50 mg per 5 mL	63323-851-15
Hydromorphone Hydrochloride Injection, USP High Potency Formula (HPF) CII Single Dose Amber Vial (HPF)	500 mg per 50 mL	63323-851-50

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Table 2. Other Currently Available Schedule-II Controlled Substances

Product	Strength	Unit of Sale NDC
Fentanyl Citrate Injection, USP CII Single Dose Simplist® Prefilled Syringe	50 mcg per 1 mL	63323-808-11
Fentanyl Citrate Injection, USP CII Single Dose Simplist® Prefilled Syringe	100 mcg per 2 mL	63323-810-20
Fentanyl Citrate Injection, USP CII Single Dose Vial	50 mcg per 1 mL	63323-806-01
Fentanyl Citrate Injection, USP CII Single Dose Vial	250 mcg per 5 mL	63323-806-05
Fentanyl Citrate Injection, USP CII Single Dose Vial	1,000 mcg per 20 mL	63323-806-20
Fentanyl Citrate Injection, USP CII Single Dose Vial	2,500 mcg per 50 mL	63323-806-50
Morphine Sulfate Injection, USP CII Single Dose Simplist® Prefilled Syringe	2 mg per 1 mL	76045-004-11
Morphine Sulfate Injection, USP CII Single Dose Simplist® Prefilled Syringe	4 mg per 1 mL	76045-005-11
Morphine Sulfate Injection, USP CII Single Dose Amber Vial	2 mg per 1 mL	63323-452-01
Morphine Sulfate Injection, USP CII Single Dose Amber Vial	5 mg per 1 mL	63323-455-01

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