State of California—Health and Human Services Agency
California Department of Public Health

Food and Drug Branch – Drug Recalls

CALIFORNIA DRUG RECALL INFORMATION SHEET

FDA warns consumers

Hikma Pharmaceuticals USA Inc. Extends Voluntary Nationwide Recall of One Lot of Acetaminophen Injection, 1000mg/100mL (10mg/mL) Bags

Recall Date	Product Description	Recalling Firm	Recall Reason
07/22/2024	Hikma brand Acetaminophen Injection USP, 1,000 mg per 100 mL (10 mg/mL)	Hikma Pharmaceuticals PLC	Potential presence of Dexmedetomidine HCL Injection (400mcg/100mL) inside the overwrap that is labelled Acetaminophen Injection, (10mg/mL) 1000mg/100mL. If injected there are multiple potential adverse outcomes that may result including varying degrees of sedation, bradypnea, bradycardia, hypertension, and hypotension or more serious and potentially life-threatening outcomes. One adverse event was reported.

Recall Class	Product Identification	Distribution	Affected Dates
N/A	**Packaging:** Bags containing Acetaminophen injections 1,000 mg per 100 mL (10 mg/mL) Individual bag overwrap **Lot Number:** 24070381 Manufacturing date: 03/19/2024 **NDC Codes:** 0143-9386-10 0143-9386-01	Nationwide (distributed only to direct customers who were notified about the recall)	Manufacturing date: 03/19/2024 Expiration Date: September 2025

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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