

DRUG & PHARMACY ALERT

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DEA Places Tramadol into Schedule IV: Manufacturers, Dispensers, and Others Must Comply with Regulatory Controls Starting August 18th

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Effective **August 18, 2014**, the Drug Enforcement Administration (DEA) placed the centrally acting opioid analgesic tramadol into schedule IV of the Controlled Substances Act (CSA). The DEA's scheduling action will affect tramadol (marketed as ULTRAM® and also known as 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol), as well as its salts, isomers, salts of isomers, and all isomeric configurations of possible forms. The DEA based the scheduling action, in part, on the substance's potential for abuse.

As of August 18th, all persons who handle or propose to handle tramadol will be subject to the DEA's regulatory controls for security, handling, labeling, packaging, registration, and reporting. For example, starting August 18th, it will be unlawful for commercial containers of tramadol to be distributed by manufacturers without labels identifying the drug as a schedule IV controlled substance. Persons who do not want to or cannot obtain a schedule IV registration must surrender or transfer, in accordance with federal procedures, all quantities of tramadol on or before August 18th. Additionally, DEA registrants must conduct inventories of existing stocks of tramadol on hand as of the effective date of the scheduling. Noncompliance with DEA scheduling requirements can lead to sanctions, including civil and criminal actions.

Roetzel's Health, Drug & Pharmacy Law team is available to assist you with any questions regarding these regulatory changes. Please contact any of our attorneys for further information.

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