

Professional Licensing Agency
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Public Notice

Tramadol will be listed as a Schedule IV drug in accordance with the Controlled Substance Act as of August 18, 2014. The requirements for handling tramadol can be found [here](#).

The link will take the user to another page with the following information:

Tramadol [2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms including tramadol, warrant control in Schedule IV of the CSA (**21 U.S.C. 812(b)(4)**). Effective August 18, 2014

Requirements for Handling Tramadol

Effective August 18, 2014, persons who handle tramadol shall be subject to the CSA's Schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, import, export, research, and conduct of instructional activities, including the following:

Security. Tramadol shall be subject to Schedules III-V security requirements and would need to be handled and stored in accordance with **21 CFR 1301.71-1301.93** pursuant to **21 U.S.C. 821, 823, and 871(b)**.

Labeling and Packaging. All labels and labeling for commercial containers of tramadol distributed on or after August 18, 2014 shall be in accordance with **21 CFR 1302.03-1302.07**, pursuant to **21 U.S.C. 825, and 958(e)**.

Inventory. Every DEA registrant who possesses any quantity of tramadol on August 18, 2014 rule shall be required to take an inventory of all stocks of tramadol on hand as of the effective date of the rule, pursuant to **21 U.S.C. 827, 958(e)**, and in accordance with **21 CFR 1304.03, 1304.04, and 1304.11(a)** and (d).

Records. All registrants shall be required to maintain records for tramadol or products containing tramadol pursuant to **21 U.S.C. 827, 958(e)**, and in accordance with **21 CFR parts 1304 and 1312**, including reports to Automation of Reports and Consolidated Orders System (ARCOS).

Prescriptions. All prescriptions for tramadol or prescriptions for products containing tramadol shall be required to be issued pursuant to **21 U.S.C. 829** and in accordance with **21 CFR part 1306**.

Pharmacies will be required to report all Tramadol prescription records that are more than a 72-hour supply to INSPECT.