

DEA Finalizes Rule to Schedule Tramadol

On July 2, 2014, the Drug Enforcement Administration (DEA) published its Final Rule in the Federal Register placing tramadol into Schedule IV effective August 18, 2014. (Tramadol is a centrally acting opioid analgesic first approved for use in the U.S. in 1995 under the name "Ultram". Since then, the Food and Drug Administration (FDA) has approved for marketing generic, combination and extended release versions.) By making tramadol a Schedule IV controlled substance, the DEA makes it easier for the pharmaceutical industry to develop consistent policies and procedures nationwide for how this drug is handled.

Acknowledging that changes such as these take time to implement, the DEA extended the usual effective date for this type of change from 30 to 45 days to provide what it considers to be "reasonable time for registrants to comply with handling requirements for a schedule IV" drug, such as moving tramadol products into a warehouse cage or adjusting suspicious monitoring systems to include tramadol orders.

It is important to note that as of August 18, 2014, manufacturers are required to print the designation "C-IV" onto every bottle and it is unlawful for commercial containers of tramadol to be distributed without that designation. The DEA believes that the 45 day window between July 2nd and August 18th will "provide a reasonable time for distributors to sell existing stock" without the designation and to stock inventory with the proper designation. Also, on August 18, 2014, every DEA registrant possessing tramadol must take an inventory of all tramadol stock in compliance with 21 C.F.R. § 1304.11(d). Anyone who doesn't want to handle controlled substances, but that currently stocks tramadol, must surrender the stock according to § 1307.21 or must transfer the stock to a DEA registrant before August 18th.