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Client Alert

Special Matters & Government Investigations Practice Group

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DEA Schedules Tramadol As A Schedule IV Controlled Substance

Summary

On July 2, 2014, the Drug Enforcement Administration (DEA) published its Final Rule placing tramadol into Schedule IV of the Controlled Substances Act (CSA).[1]

Tramadol is a synthetic opioid analgesic used in the treatment of pain, and brand names for the substance include Ultram®, Ultram ER®, Ultracet®, and ConZip®.

Tramadol initially was approved for marketing in 1995, but the drug was not scheduled under the CSA at that time. DEA's rescheduling of tramadol comes at a time of growing concerns relating to abuse and misuse of opioid analgesics. Tramadol increasingly is abused in combination with other controlled substances. One commenter described tramadol as a "loop hole drug" that is "addictive, abused, and diverted" but that may have not been considered dangerous because it was not controlled.[2] Notably, a number of states already had scheduled tramadol as a controlled substance, including Arkansas, Illinois, Kentucky, Mississippi, New Mexico, North Dakota, Oklahoma, Tennessee and Wyoming.

Implications

The scheduling of tramadol as a Schedule IV drug will impose stricter regulatory controls on all persons that handle tramadol products, including manufacturers, distributors, prescribers, dispensers, importers, exporters, and researchers. Violations of these regulatory controls can result in administrative, civil and/or criminal sanctions.

In order to give registrants sufficient time to comply with the various requirements applicable to Schedule IV controlled substances, DEA extended the usual time period for final implementation from 30 days to 45 days. As such, the Final Rule rescheduling tramadol will not take effect until August 18, 2014.

Beginning August 18, 2014 registrants will be required to comply with all inventory, labeling, prescription, recordkeeping, reporting, security, and other

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requirements for Schedule IV controlled substances including, but not limited to, the following:

- Conducting an initial and biannual inventories;
- Complying with labeling requirements, including the requirement that manufacturers print the designation "C-IV" on the label for each container of tramadol they distribute;
- Complying with written and oral prescription requirements, including the requirement that prescriptions not be filled or refilled more than six months after the prescription date;
- Maintaining records regarding tramadol for at least two years;
- Notifying DEA in the event of any theft or significant loss of tramadol;
- Moving tramadol products into distribution center cages that comply with CSA security requirements; and
- Ensuring suspicious order monitoring systems are reviewing tramadol orders.

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[1] *See* 79 Fed. Reg. at 37623 (July 2, 2014).
[2] *See* 79 Fed. Reg. at 37624 (July 2, 2014).