

## **DEA Federally Controls Carisoprodol as a Schedule IV Substance, Establishes Regulatory Timeline**

By [Larry K. Houck](#) –

The Drug Enforcement Administration (“DEA”) published its long awaited [final rule](#) in the [Federal Register](#) today (76 Fed. Reg. 77,330 (Dec. 12, 2011)) placing carisoprodol into schedule IV of the federal Controlled Substances Act (“CSA”). Federal scheduling of carisoprodol follows control of the drug by eighteen states around the country. Effective January 12, 2012, DEA’s placement pertains to carisoprodol (widely distributed under the trade name of Soma®), and its salts, isomers and salts of isomers.

DEA’s placement of carisoprodol in schedule IV subjects manufacturers, distributors, dispensers such as pharmacies and physicians, importers, exporters, and anyone in possession of the drug to the applicable provisions of the CSA and its implementing regulations, including administrative, civil and criminal sanctions.

DEA’s final rule establishes the following timetable:

- a. Manufacturers, distributors, dispensers, importers, exporters, researchers, and persons conducting instructional and chemical analysis must submit an application for registration to DEA by January 11, 2012. Entities currently conducting these activities may continue until DEA has approved or denied their application for registration;
- b. Entities electing not to obtain a DEA registration, or who cannot obtain a registration, must surrender all stocks of carisoprodol pursuant to 21 C.F.R. § 1307.21 on or before January 11, 2012. Entities may, in the alternative, transfer all carisoprodol to a DEA registrant who is authorized to possess schedule IV controlled substances on or before January 11, 2012;
- c. Carisoprodol will generally be subject to the security requirements applicable to schedule IV controlled substances as of January 11, 2012. However, certain storage, manufacturing and freight forwarding security requirements under 21 C.F.R. §§ 1301.72(b) and (c), 1301.73 and 1301.77 are not applicable until April 10, 2012;
- d. Commercial containers of carisoprodol packaged on or after April 10, 2012 must be labeled as “C-IV” and packaged in accordance with 21 C.F.R. §§ 1302.03-.07. Registrants may distribute commercial containers packaged before April 10, 2012 that do not comply with 21 C.F.R. §§ 1302.03-.07 until June 11, 2012. All commercial containers of carisoprodol must be labeled as “C-IV” and comply with 21 C.F.R. §§ 1302.03-.07 on or after June 11, 2012;
- e. Registrants who possess any quantity of carisoprodol must take an initial inventory of all stocks on-hand on or before January 11, 2012 and then include carisoprodol in its biennial inventory thereafter;
- f. Registrants who possess any quantity of carisoprodol must maintain all records required for schedule IV controlled substances after January 11, 2012;

g. All prescriptions for carisoprodol or prescriptions containing carisoprodol must comply with DEA's controlled substance prescription requirements after January 11, 2012;

h. Carisoprodol is subject to importation and exportation requirements after January 11, 2012;  
and

i. Any activity with carisoprodol that is not authorized by, or that is conducted in violation of, the CSA on or after January 12, 2012, is unlawful.