

requirements for possessing and dispensing controlled substances, including the issuance of a prescription for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a). A prescription serves as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed. The prescription also provides a record of the actual dispensing of the controlled substance to the ultimate user (the patient) and, therefore, is critical to documenting that controlled substances held by a pharmacy have been dispensed. The maintenance of complete and accurate records is an essential part of the closed system of distribution established by Congress.

Electronic Prescriptions for Controlled Substances

Historically, where federal law required that a prescription for a controlled substance be issued in writing, that requirement could only be satisfied through the issuance of a paper prescription. Given advancements in technology and security capabilities for electronic applications, DEA amended its regulations to provide practitioners with the option of issuing electronic prescriptions for controlled substances in lieu of paper prescriptions. DEA's Interim Final Rule for Electronic Prescriptions for Controlled Substances was published on March 31, 2010, at 75 FR 16236-16319, and became effective on June 1, 2010.

Update

Certifying Organization With a Certification Process Approved by DEA Pursuant to 21 CFR 1311.300(e)

The Interim Final Rule and the DEA's Electronic Prescriptions for Controlled Substances Clarification (76 FR 64813) provides that, as an alternative to the third-party audit requirements of 21 CFR 1311.300(a) through (d), an electronic prescription or pharmacy application may be verified and certified as meeting the requirements of 21 CFR part 1311 by a certifying organization whose certification process has been approved by DEA. The preamble to the Interim Final Rule further indicated that, once a certifying organization's certification process has been approved by DEA in accordance with 21 CFR 1311.300(e), such

information will be posted on DEA's Web site. 75 FR 16243 (March 31, 2010). On July 25, 2014, DEA approved the certification process developed by ComplySmart, LLC. Relevant information has been posted on DEA's Web site at <http://www.DEAdiversion.usdoj.gov>.

Dated: August 11, 2014.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: United States Pharmacopeial Convention

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before September 19, 2014. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 19, 2014.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of importers, of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR pt. 0, subpt. R, App.

In accordance with 21 CFR 1301.34(a), this is notice that on February 10, 2014, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852, applied to be

registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Cathinone (1235)	I
Methaqualone (2565)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
4-Methyl-2,5-dimethoxyamphetamine (7395).	I
3,4-Methylenedioxyamphetamine (7400).	I
Codeine-N-oxide (9053)	I
Difenoxin (9168)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Norlevorphanol (9634)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Phenmetrazine (1631)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Phencyclidine (7471)	II
4-Anilino-N-phenethyl-4-piperidine (8333).	II
Phenylacetone (8501)	II
Alphaprodine (9010)	II
Anileridine (9020)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Sufentanil (9740)	II

The company plans to import reference standards for sale to researchers and analytical labs.

The company plans to import the listed controlled substances in bulk powder form from foreign sources for the manufacture of analytical reference standards for sale to their customers.

Dated: August 11, 2014.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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