



U. S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

www.dea.gov

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Dear Registrant,

On August 22, 2014, the Drug Enforcement Administration (DEA) published in the Federal Register the final rule placing hydrocodone combination products (HCPs) into Schedule II of the Controlled Substances Act (CSA), effective October 6, 2014. The final rule is available at www.regulations.gov and on the DEA Office of Diversion Control website at www.DEADiversion.usdoj.gov.

The rule imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule II controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, conduct chemical analysis with, or possess), or propose to handle HCPs. For non-practitioner registrants (e.g., manufacturers, distributors, reverse distributors, importers, exporters, and narcotic treatment programs), the regulations governing the physical security requirements for Schedule II controlled substances are outlined in Title 21, Code of Federal Regulations, Section 1301.72 (21 C.F.R. § 1301.72), which is provided below for your convenience.

§1301.72: Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) *Schedules I and II.* Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas:

- (1) Where small quantities permit, a safe or steel cabinet;
 - (i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
 - (ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and
 - (iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

Should you have any questions pertaining to this matter, please contact your local DEA field office. The DEA Field Office which has jurisdiction over the area where you are located can be found on the DEA Office of Diversion Control website, on the About Us webpage.

Sincerely,



Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control