U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

APR 2 9 2008

Dear DEA Registrant Handling the List I Chemical Iodine:

On July 2, 2007, the Drug Enforcement Administration (DEA) published in the Federal Register the Final Rule changing the regulation of the listed chemical iodine under the chemical regulatory provisions of the Controlled Substances Act (CSA). The rule may be found at 72 FR 35920 (corrected at 72 FR 40238, July 24, 2007; corrected at 72 FR 41820, July 31, 2007). This letter provides information regarding the requirements for registration for the handling of iodine.

DEA controlled substance registrants are not permitted to distribute List I chemicals utilizing their DEA controlled substance registrations unless they meet the specific requirements of Title 21 Code of Federal Regulations (21 CFR) § 1309.24(b). Thus, the purpose of this correspondence is to remind persons that, in most cases, they are required to obtain a separate DEA chemical registration if they handle regulated iodine materials in excess of 2.2 percent concentration.

21 CFR § 1309.24(b) waives the registration requirement "for any person who distributes a product containing a List I chemical that is regulated pursuant to § 1300.02(b)(28)(i)(D), if that person is registered ... to manufacture, distribute or dispense a controlled substance." The term "a product containing a List I chemical is regulated pursuant to §1300.02(b)(28)(i)(D)" means: "... a listed chemical that is contained in a drug ... that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, ...". The DEA notes that neither § 1309.24(b) nor § 1300.02(b)(28)(i)(D) were amended or revised by the Final Rule published July 2, 2007. Thus, for the requirement of a separate chemical registration to be waived for a controlled substances registrant, that registrant must demonstrate to DEA that the drug product containing iodine is marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act.

In DEA's experience, the vast majority of the iodine being regulated by the Final Rule, that is, iodine in excess of 2.2 percent concentration, does not meet the parameters of §1300.02(b)(28)(i)(D). Therefore, controlled substances manufacturers, distributors, and dispensers of these materials must obtain a separate chemical registration to handle regulated forms of iodine.

The Final Rule, published July 2, 2007, removes deficiencies that were in the regulatory controls, which have been exploited by drug traffickers who divert iodine (in the form of iodine crystals and iodine tincture) for the illicit production of methamphetamine in clandestine drug laboratories. The rulemaking moved iodine from List II to List I; reduced the iodine threshold from 0.4 kilograms to zero kilograms; added import and export regulatory controls; and added controls on chemical mixtures containing greater than 2.2 percent iodine. The rulemaking also established regulatory controls that apply to iodine crystals and iodine chemical mixtures that contain greater

than 2.2 percent iodine concentration. The regulation therefore controls iodine crystals and strong iodine tinctures/solutions (e.g., 7 percent iodine) that do not have common household uses and instead have limited application in livestock, horses, and for disinfection of equipment. Household products such as 2 percent iodine tincture/solution and household disinfectants containing iodine complexes are not adversely impacted by the regulation. Additionally, the Final Rule exempted transactions of povidone-iodine products and Lugol's Solution USP one-fluid-ounce (30 ml) or less in original manufacturer's packaging, and no greater than one package/bottle per transaction.

In addition to the chemical registration requirements, regulated persons are subject to the import/export notification requirements of the CSA, and are required to maintain records of all regulated transactions involving iodine, regardless of size. The rule became effective August 1, 2007. In order to continue business pending final action by the DEA on their application, persons seeking chemical registrations to handle these materials were to have applied by August 31, 2007. If your business is handling iodine over 2.2 percent, is not registered by DEA to handle List I chemicals, or did not apply for such registration by the August 31, 2007 deadline, it must cease activity in this area.

The Final Rule is available for review on the DEA Diversion Control Program website at www.DEAdiversion.usdoj.gov. To access the Rule, from the home page, click on Federal Register Notices mid-way down in the left-hand column; click on Rules; click on 2007; the iodine Final Rule is the 5th bullet in the list.

Questions regarding the content of the rule may be directed to the Drug and Chemical Evaluation Section, Office of Diversion Control, DEA at (202) 307-7183. Questions regarding the registration process may be directed to the DEA's Registration Unit at 1-800-882-9539.

Sincerely,

Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control