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

www.dea.gov

September 9, 2014

Dear Registrant:

On September 9, 2014, the Disposal of Controlled Substances final rule was published in the *Federal Register*. The final rule is available at http://www.regulations.gov and the Drug Enforcement Administration (DEA) website, http://www.DEAdiversion.usdoj.gov. The final rule will become effective on October 9, 2014.

These regulations implement the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act). The Disposal Act was passed in an effort to curtail prescription drug abuse by authorizing regulations that outline methods for ultimate users to dispose of their unused or unwanted pharmaceutical controlled substances. The final rule authorizes ultimate users to transfer unwanted and unused pharmaceutical controlled substances in their lawful possession to an authorized collector for safe, secure, and responsible disposal. In addition to ultimate users, long-term care facilities and persons lawfully entitled to dispose of a decedent's property may also transfer pharmaceutical controlled substances to an authorized collector for the purpose of disposal.

The new rule also establishes regulations related to each element of the disposal process, including the transfer, delivery, collection, destruction, return, and recall of pharmaceutical controlled substances, by both registrants and non-registrants. These regulations are incorporated into a new 21 C.F.R. part 1317 on disposal. The final rule and supporting documents describe in detail the new collection programs and the various changes to the existing regulations. Several important requirements are summarized below. This letter is not a complete list of all changes, nor does it detail the nuances of the various requirements. Please consult the final rule, the Code of Federal Regulations, or your local DEA field office for detailed information.

Collection from Ultimate Users

Authorized collectors may collect pharmaceutical controlled substances from ultimate users using one of the following methods: **collection receptacles**, or **mail-back programs**. The following categories of registrants may modify their registration to become collectors if they are authorized to handle schedule II controlled substances: **manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics** with an on-site pharmacy, and **retail pharmacies**. These registrants may modify their registrations to become authorized collectors online at http://www.DEAdiversion.usdoj.gov. There is no fee to modify a registration for this

purpose. Authorized collectors may maintain collection receptacles at their registered locations; and they may operate a mail-back program as long as they have an on-site means of destruction for the mail-back packages. Retail pharmacies and hospitals/clinics with an on-site pharmacy may manage collection receptacles at long-term care facilities.

Law enforcement continues to have autonomy with respect to how they collect pharmaceutical controlled substances from ultimate users, including maintaining collection receptacles, and conducting mail-back programs and take-back events.

The new rule also outlines the security controls and other reporting and recordkeeping requirements associated with collection activities. Many of these requirements are contained in the new part 1317, and some requirements are contained in revised parts 1301, 1304, and 1305. The new rule does not require any registrant to become a collector. Becoming a collector is voluntary.

Summary of Modifications to Current Regulations

21 C.F.R. Part 1307: The new rule eliminates existing 21 C.F.R. 1307.12 and 1307.21, which outline requirements for registrant and non-registrant disposal, including return and recall. The new part 1317 contains the requirements on disposal procedure and security, collection of pharmaceutical controlled substances from ultimate users, return and recall, and destruction of controlled substances.

DEA Form 41: This form must be used to record the destruction of all controlled substance inventory, as well as the destruction of pharmaceutical controlled substances that are collected from ultimate users. The form is available online at http://www.DEAdiversion.usdoj.gov. Note that a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (*e.g.*, some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as "drug wastage" and "pharmaceutical wastage"). Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations (*e.g.*, 21 C.F.R. 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

DEA Form 106: This form must be used by registrants to report the theft or loss of any controlled substance, including sealed inner liners and returned mail-back packages. It has been updated to include the collection of information relevant to lost or stolen sealed inner liners and returned mail-back packages.

Reverse Distributors: A *reverse distributor* will be defined as a person *registered* as a reverse distributor. *Reverse distribute* means to acquire controlled substances from another registrant or law enforcement for the purpose of return or destruction. Title 21 C.F.R. parts 1301 and 1304 have been revised to include security, inventory, recordkeeping, and other requirements and procedures pertinent to persons who reverse distribute. This distinction between "reverse distributors" and "those who reverse distribute" is necessary because these new requirements and procedures also apply to certain, specified entities that are permitted to reverse distribute in certain circumstances, even though they are not registered as reverse distributors. One important new requirement is that those entities who reverse distribute must destroy controlled substances received for the purpose of destruction within 30 calendar days of receipt. Day 1 is the day the substances are physically acquired through pick-up or delivery.

Recordkeeping: 21 C.F.R. Part 1304 has been revised to include inventory and recordkeeping requirements pertinent to authorized collectors, reverse distributors, and any other person who reverse distributes.

Return and Recall: The previous regulations regarding return and recall in 21 C.F.R. 1307.12 will be eliminated upon the effective date of the final rule. Return and recall requirements, including recordkeeping, are outlined in 21 C.F.R. parts 1304, 1305, and 1317.

Destruction of Controlled Substances: The final rule implements a standard of destruction: *non-retrievable*. The process utilized to render a substance "non-retrievable" shall permanently alter the substance's physical or chemical condition or state through irreversible means and thereby render the substance unavailable and unusable for all practical purposes. A substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

Two-Person Integrity Requirement for Transport and Destruction: When transporting to destroy controlled substances at an off-site location, two employees of the registrant must accompany the controlled substances, observe the loading and unloading of the controlled substances, and observe the destruction of the controlled substances. Additionally, the names and signatures of the two employees that witnessed the destruction must be recorded on DEA Form 41.

Memorandums of Understanding (MOUs) and Memorandums of Agreement (MOAs): The final rule eliminates all existing MOUs and MOAs that registrants may have pursuant to 21 C.F.R. 1307.21. Practitioners may request a new MOU or MOA pursuant to the new 21 C.F.R. 1317.05. Please contact your local DEA field office for assistance.

The DEA looks forward to continuing to work in partnership with our registrants to maintain the integrity of the closed system of distribution for controlled substances. If you have any questions

regarding the new regulations, please see our website, http://www.DEAdiversion.usdoj.gov, or contact your local DEA field office.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control