Drug Enforcement Administration Diversion Control Division Guidance Document

Title: Reporting Regulated Transactions Involving Listed Chemicals

Summary: This guidance document provides clarification regarding the regulatory requirement for persons engaging in regulated transactions in listed chemicals to report transactions involving an extraordinary quantity, an uncommon method of payment or delivery, or other circumstances indicating a potential use of listed chemicals in violation of the law. This guidance is being sent via email to all Drug Enforcement Administration (DEA) listed chemical registrants and regulated persons.

To Whom It Applies: DEA Listed Chemical Registrants and Regulated Persons

Dear Listed Chemical Registrant/Regulated Person:

A "regulated person" is "any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine." <u>21 CFR</u> <u>1300.02(b)</u>. "Regulated transaction" is defined in <u>21 CFR 1300.02(b)</u> and includes certain distributions, receipts, sales, importations, and exportations of listed chemicals.

The Drug Enforcement Administration's (DEA) Diversion Control Division reminds all "regulated persons," whether or not they are registered with DEA as chemical handlers, of the requirement to "report to the Special Agent in Charge [SAC] of the DEA Divisional Office ...

any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of" the DEA regulations in <u>21 CFR part</u> <u>1310</u>. DEA refers to these as <u>21 CFR 1310.05(a)(1)</u> reports. DEA regulations require regulated persons to orally report such transactions to the appropriate SAC at the earliest practicable opportunity after becoming aware of the circumstances involved, and to file a written report of the transaction within 15 calendar days after becoming aware of the circumstances of the event. <u>21 CFR 1310.05(a)(1)</u>. Written reports must contain the information specified in <u>21 CFR 1310.06(c)</u>.

The regulations require the written <u>21 CFR 1310.05(a)(1)</u> reports to be filed with the relevant SAC. In order to facilitate a paperless option, DEA has created a link on our DEA Diversion website with an online form by which these written <u>21 CFR 1310.05(a)(1)</u> reports may be submitted. The form will be submitted to both DEA Headquarters and the appropriate SAC, on behalf of the regulated person. The online form can be found at <u>https://apps.deadiversion.usdoj.gov/CORT</u>. DEA will continue to accept written reports on paper as well.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or department policies. DEA Listed Chemical Registrants and Regulated Persons

For more information regarding DEA's Diversion Control Division, please visit

www.DEAdiversion.usdoj.gov. If you have any additional questions on this matter, please contact

the DEA Diversion Control Division's Chemical Investigation Section at <u>CORT@dea.gov</u>.

Sincerely,

Thomas W. Prevoznik Acting Assistant Administrator Diversion Control Division

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