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Legal Issues Pertaining to Listed Chemicals

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Agenda

- “Orders to Show Cause” against regulated sellers and mail order distributors of scheduled listed chemical products (SLCP)
- Implications of CMEA’s regulated seller/mail order distributor requirements for chemical distributors, manufacturers, and importers
- New importation criteria for ephedrine, pseudoephedrine, and phenylpropanolamine
- Questions and Answers

“Orders to Show Cause” Against Regulated Sellers/Mail Order Distributors

- Legal Authority: 21 USC 842(c)(4)(A) – order may prohibit regulated seller or mail order distributor from selling SLCP
- Procedures: DEA will use the procedures set forth in 21 USC 824(c)

“Orders to Show Cause” Against Regulated Sellers/Mail Order Distributors

- Order may be issued for violating 21 USC 842(a)(12):
 - Daily sales limit of 3.6 grams (base) per purchaser regardless of the number of transactions (21 USC 830(d)(1))
 - Knowledge (independent of consulting logbook)

****Does “knowledge” require actual knowledge? May it also refer to sales when the seller “should have known?”****

“Orders to Show Cause” Against Regulated Sellers/Mail Order Distributors

- Order may be issued for violating 21 USC 842(a)(12):
 - Selling at retail a SLCP in nonliquid form unless the product is packaged in blister packs containing no more than 2 dosage units, or (if blister packaging is not feasible) in single dose packets or pouches (21 USC 830(d)(2))

“Orders to Show Cause” Against Retail Sellers

- Order may be issued against regulated seller for violating 21 USC 842(a)(13):
 - Knowing or reckless violation of 21 USC 830(e). Section 830(e) requirements include
 - Seller is self-certified
 - Employee training
 - Seller maintains records of training and copy of certification
 - Product placement
 - Deliver product directly to the purchaser
 - Logbook (60 milligrams or less of pseudoephedrine exception)

Entries in Logbook

- Purchaser and seller make required entries in logbook for sales governed by the logbook requirement
 - Purchaser presents required identification
 - Purchaser signs the logbook and enters name, address, date and time of sale
 - Seller verifies name in logbook corresponds to name on purchaser's identification
 - Seller enters name of product and quantity sold
 - Logbook contains required warning regarding false statements and applicable penalties
 - Seller maintains logbook for not fewer than two years after date of entry in logbook

Implications of CMEA for Chemical Distributors, Manufacturers, and Importers

- Will selling SLCP to a particular regulated seller or mail order distributor have an impact on a distributor's DEA registration?
 - Know the law
 - Know your obligations under the law
 - Know your customers
 - Know your customers' obligations under the law

Public Interest Factors Pertaining to Registration of Distributors

- Distributors must “maintain effective controls against diversion of listed chemicals into other than legitimate channels.” 21 USC 823(h)(1)
- Distributors must comply with Federal, State, and local law. 21 USC 823(h)(2)
- Distributors must conduct business in a manner that is “consistent with the public health and safety.” 21 USC 823(h)(5)

****Is the Distribution Legitimate?****

- If the distribution of SLCP is to an entity that cannot legally sell the product, the product is not being distributed in “legitimate channels”
- If the distributor’s customer is not complying with the law, the distribution is not consistent with the public health and safety
- Products that are not packaged for lawful sale cannot be distributed for sale consistent with the public health and safety

****Avoiding Pitfalls****

- Regulated sellers must maintain a copy of their certification – ask for a copy
- Train sales and delivery personnel to look for “red flags”
- Volume, volume, volume!

New Importation Criteria EPH, PSE, and PPA

- 21 USC 971 – DEA may suspend any importation of a listed chemical on the ground that the chemical may be diverted to the clandestine manufacture of controlled substances
- 21 USC 952 – DEA shall only allow importation of EPH, PSE, and PPA that DEA finds **necessary** to provide for medical, scientific, or other legitimate purposes
 - Same standard that is used for allowing importation of narcotic raw material