Administrative Actions

Office of Diversion Control Operations
Pharmaceutical Investigations Section (DOP)
Section Chief Kerry R. Hamilton

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Objectives

- Define DEA Diversion Control Division's mission
- Provide C.F.R. citation that gives DEA authority to conduct inspections
- List registrants subject to scheduled investigations every one to five years
- Outline administrative actions DEA may take in response to deficiencies discovered during scheduled investigations

MISSION

The Diversion Control Division's mission is to prevent, detect and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels while ensuring an adequate and uninterrupted supply of pharmaceutical controlled substances and listed chemicals to meet legitimate medical, commercial and scientific needs.

MISSION

Diversion Control Division accomplishes this mission by:

- **Scheduling controlled substances,**
- **Setting production quotas for certain controlled substances and regulated chemicals,**
- **Establishing import and export controls,**
- **Conducting liaison with industry and associations representing registrants,**
- **Assisting state and local authorities,**
- **Maintaining international liaison and representing the United States on matters relating to controlled substances and regulated chemicals at the United Nations, and**
- **Investigating DEA registrants to detect diversion, and, where diversion occurs, prosecuting violators.**

21 C.F.R. 1316.03

In carrying out his functions under the Act, the Administrator, through his inspectors, is authorized in accordance with sections 510 and 1015 of the Act (21 U.S.C. 880 and 965) to enter controlled premises and conduct administrative inspections thereof, for the purpose of:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and regulations promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to part 1304 of this chapter, order form records required to be kept pursuant to part 1305 of this chapter, prescription and distribution records required to be kept pursuant to part 1306 of this chapter, records of listed chemicals, tableting machines, and encapsulating machines required to be kept pursuant to part 1310 of this chapter, import/export records of listed chemicals required to be kept pursuant to part 1313 of this chapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage.

Scheduled Investigations

Registrants requiring scheduled investigation every one to five years:

- **Controlled Substance Manufacturers (Bulk, Dosage Form, Repackager or Relabeler)**
- **Distributors**
- **Reverse Distributors**
- **Importers**
- **Exporters**
- **Narcotic Treatment Programs**

*All Schedule I and II Bulk Manufacturers and all Schedule I and II Importers are subject to a Section 303 Investigation which is to be conducted annually before a registrant may renew or modify its registration and/or before any new applicant can be approved.

Scheduled Investigations

- **Work Plan established every fiscal year**
- **While called scheduled, the registrant typically does not receive prior notice**
- **Includes review of records, reports, security, and an accountability of controlled substances or listed chemicals**
- **Where an investigation reveals violations of the CSA and its implementing regulations, action is required by DEA**

Administrative Actions

- **On the Spot Correction**
- **Letter of Admonition**
- **Memorandum of Agreement**
- **Order to Show Cause**
- **Immediate Suspension order**

On the Spot Correction

- **Some issues may be corrected on the spot (e.g., certain recordkeeping violations, security issues that do not involve the diversion of controlled substances)**
- **Firm management is still notified of the deficiencies discovered**
- **Issue is still documented in report**

Letter of Admonition

- **Formally advises the registrant in writing of any violations identified**
- **Detailed explanation of all violations**
- **Allows for voluntary corrective action by the registrant**
- **Makes the violations a matter of record should the same violations be encountered at a later date**

Memorandum of Agreement

- **Formally documents findings of the investigation**
- **Memorializes agreement between the registrant and DEA**
- **May include terms that go beyond the record-keeping, reporting, or security requirements identified in the Code of Federal Regulations**

Memorandum of Agreement

- **May mirror state board action**
- **May restrict or limit access to controlled substances**
- **All manufacturers, distributors, importers, exporters and NTPs placed under a MOA shall be inspected one year after the effective date of the MOA and every two years until the MOA expires**

Order to Show Cause

- **May be issued for revocation of an existing DEA registration or for the denial of an application for registration**
- **Grounds include:**
  - **Felony conviction under the CSA or any other law of the United States, or of any state, relating to any substance defined as a controlled substance or List I chemical**
  - **Material falsification of any application filed pursuant to or required by the CSA**

Order to Show Cause

- **License or registration suspended, revoked, or denied by a competent state authority and is no longer authorized by state law to engage in the manufacturing, distribution, or dispensing of controlled substances or List I chemicals**
- **Suspension, revocation, or denial of their registration recommended by competent state authority**

Order to Show Cause

- **Exclusion from participation in any federal health care program (Medicare/Medicaid)**
- **Committed such acts as would render their registration inconsistent with the public interest - 21 U.S.C. 824(a)(4)**

Immediate Suspension Order

Due to failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of registrants under the CSA, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration