DRUG ENFORCEMENT ADMINISTRATION

Supply Chain Conference 2024

Research versus Manufacturing
UN Reporting and Quota Section
Diversion Control Division

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Little Rock, Arkansas

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Policy Statement: Clarification of Coincident Activities for Researchers

Federal Register October 31, 1995 (60 FR 55310)

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[DEA No. 131N]

Clarification of Coincident Activities for Researchers

AGENCY: Drug Enforcement Administration, DOJ.

ACTION: Policy Statement.

60 FR 55310 (Oct. 31, 1995)

Research vs. Manufacturing

Generally, Research and Manufacturing are designated as independent activities for which separate DEA registrations are required

Research vs. Manufacturing Activities

Research

- Synthesis route
- Process parameters in lab
- Adhesive studies
- Laboratory testing
- Dosage release rate studies

Manufacturing

- Granulation development
- Validation
- Dosage forms for approval and testing, including clinical trials
- Stability
- Exhibit batches
- Rework processes

Researcher Registration

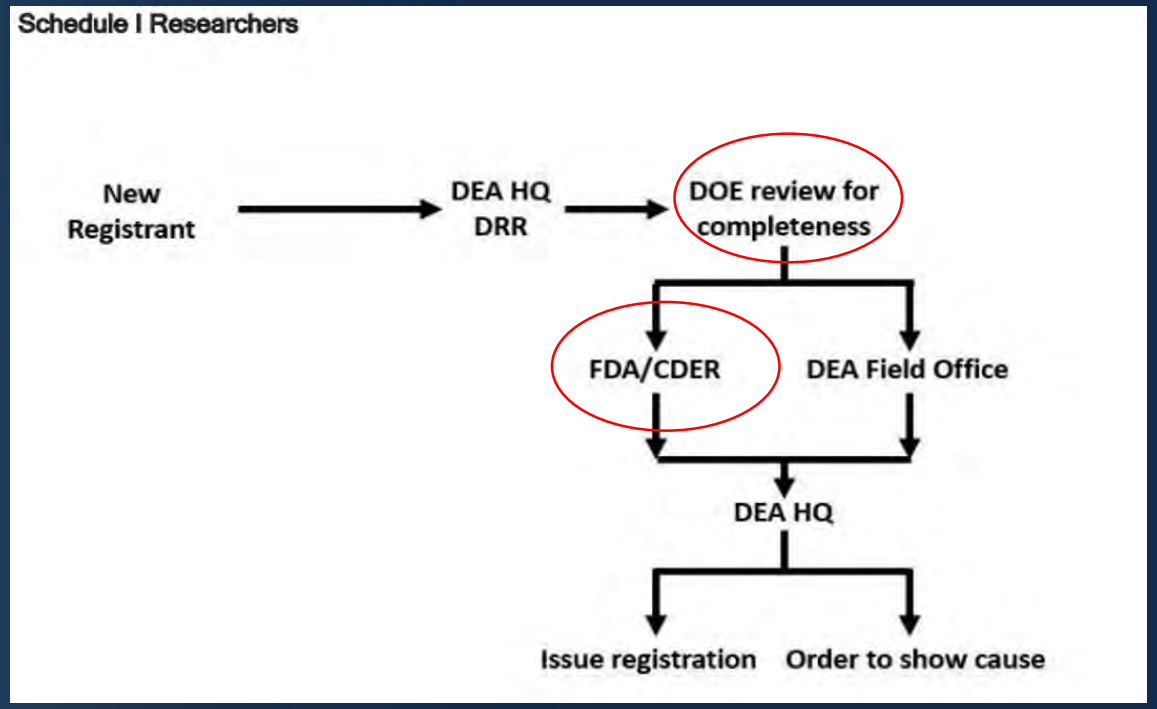
There are two separate categories for researcher registration which are based on controlled substance schedules:

- **Schedule I Researcher**
- **Schedule II-V Researcher**

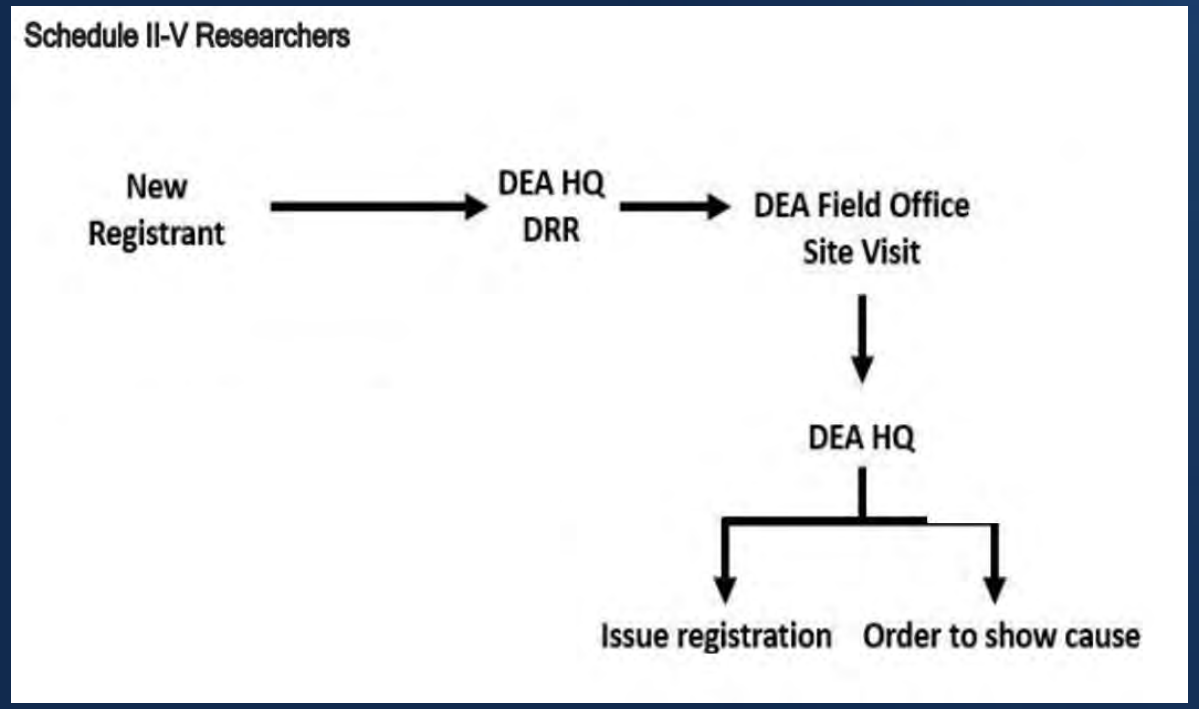
If a researcher wishes to conduct research in schedules I and schedules II-V, they must obtain **two separate registrations**, a researcher may not have schedules I–V on one DEA registration. 21 CFR 1301.13(e).

Schedule I vs Schedule II-V Researcher Registration

Schedule I



Schedule II-V



Researcher Coincident Activities

- Schedule I:
  - Manufacture or import substances for research purposes as set forth in an approved protocol as required per 21 CFR 1301.18
  - Distribute to persons registered to conduct research with such substance or to conduct chemical analysis

Researcher Coincident Activities

- Schedules II through V:
  - Conduct chemical analysis
  - Manufacture as set forth in a statement filed
  - Import substances for research purposes
  - Distribute to persons registered to conduct research and chemical analysis
  - Conduct instructional activities

Researcher Coincident Activities

Small amounts may be manufactured **if** the quantities are set forth in a statement filed with the application for registration, **AND** the purpose as set forth in the statement is to develop synthesis procedures or other research **not related to dosage form** development.

Manufacturer Coincident Activities

- Schedule I through V:
  - Distribute a substance or class for which registration was issued
- Schedule II through V:
  - Conduct chemical analysis and preclinical research with substances in the schedules authorized for manufacture

Manufacturer Activities

When the purpose is for:

- Product Development
    - bioavailability, formulation, stability and validation studies
- Establish manufacturing processes/procedures
    - pilot, scale up, reformulation studies, *etc*.
- Satisfy regulatory requirements
    - FDA submissions or good manufacturing practice

A manufacturer registration is required and **QUOTAS** apply to conduct these activities.

Coincident Activities

- 21 CFR 1301.13(e)(1)
- Coincident to the primary activity does not convey the equivalent registration
  - *e.g.* coincident distribution does not grant you a distribution registration
- Registration should reflect primary activity

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Questions?

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