



Quota Virtual Diversion Awareness Training

April 16, 2026



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Research versus Manufacturing

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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 \(Oct. 31, 1995\)](#)



Why the Clarification Statement was Issued



- Registrants were manufacturing bulk material under their research registration for the purposes of:
 - Performing dosage form development including batches required for FDA approval
 - Distributing the material to other research registrants to perform other dosage form development work
- Registration Dictates Your Primary Activity
 - Only as a coincidental activity can researchers manufacture small amounts of bulk material
 - Researchers should not be manufacturing large quantities of material
 - DEA strives to maintain a closed system of distribution





Research vs. Manufacturing

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





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).



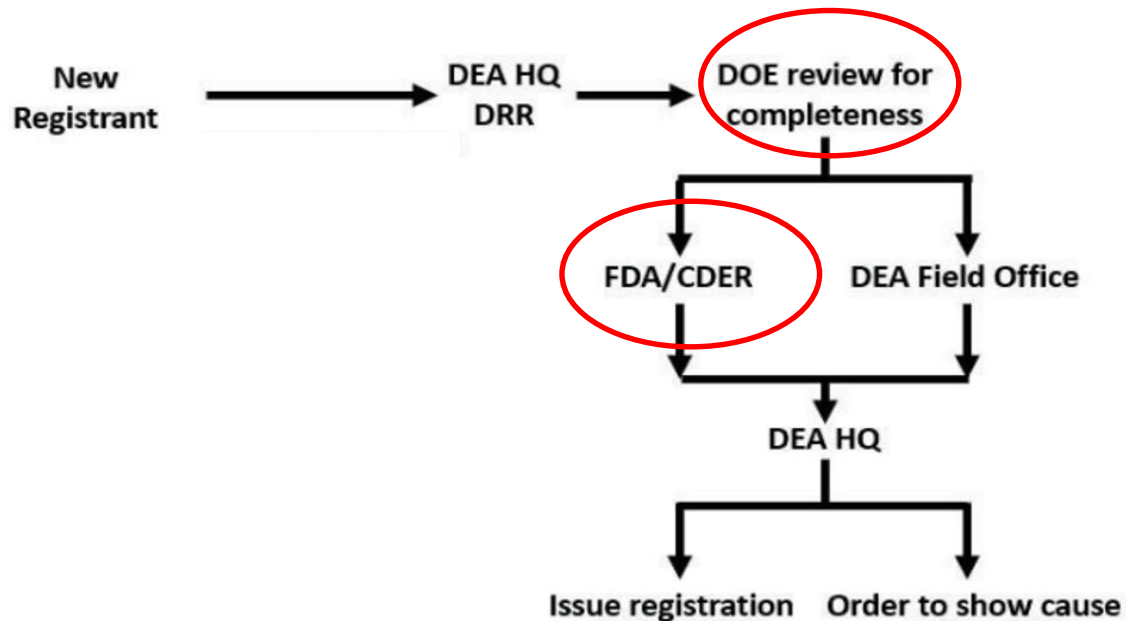


Schedule I vs Schedule II-V Researcher Registration

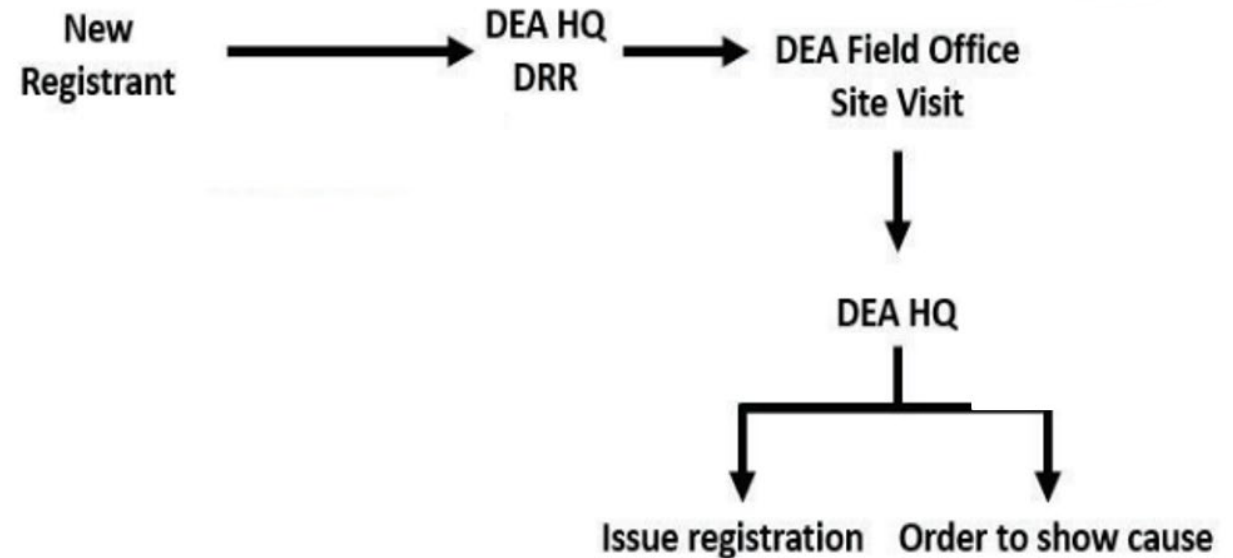
Schedule I

Schedule II-V

Schedule I Researchers



Schedule II-V Researchers





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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