RESEARCH VS MANUFACTURING

Drug Enforcement Administration
Diversion Control Division
UN Reporting and Quota Section

Pharmaceutical Training Seminar

OCTOBER 31, 1995 POLICY STATEMENT : CLARIFICATION OF COINCIDENT ACTIVITIES FOR RESEARCHERS

RESEARCH VS. MANUFACTURING

- Research and Manufacturing are designated as independent activities for which separate registrations are required with the DEA
- 21 CFR 1301.13 (e) (1) describes specific coincident activities for which separate registrations are not required

SCHEDULE I: RESEARCH COINCIDENT ACTIVITIES 21CFR1301.13(E)(1)

manufacture or import substance for which registration was issued and set forth in protocol (21 CFR 1301.18)

- distribute to persons registered to conduct research or chemical analysis with such substance

SCHEDULES II THROUGH V:

RESEARCH COINCIDENT ACTIVITIES

21 CFR 1301.13(E)(1)

chemical analysis

- ü manufacture as set forth in statement but not for dosage form development
- ü import substances for research purposes
- ü distribute to persons registered to conduct research, chemical analysis, instructional activities

RESEARCH ACTIVITIES

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

MANUFACTURING COINCIDENT ACTIVITIES 21 CFR 1301.13(E)(1)

Schedule I through V:

- ü May distribute a substance or class for which registration was issued

Schedule II through V:

- ü May distribute (as above)
- ü May conduct chemical analysis and preclinical research with substances authorized to manufacture

MANUFACTURING ACTIVITIES

- Purpose is to satisfy regulatory requirements such as FDA submissions or good manufacturing practice
- Establishing manufacturing processes and procedures (pilot, scale up, reformulation studies etc.)
- Development including bioavailability, formulation, stability and validation studies

CONCLUSION

- Once manufacturing moves beyond the scope of the research and becomes product development, those manufacturing activities are no longer considered to be coincident to research and must be conducted under a manufacturing registration
- Must meet requirements for registration as a manufacturer, i.e. **QUOTAS**

HISTORICAL DETERMINATIONS

Manufacturing	Research
n Validation batches n Dosage forms for approval and testing, including clinical trials n Stability batches n Exhibit batches n Rework processes n Granulation development	n Process parameters in laboratory n Adhesive studies n Laboratory testing n Dosage release rate studies n Conducting Clinical trials n Synthesis route

COINCIDENT ACTIVITIES

21 CFR 1301.13 (e) (1)
Coincident to the primary activity
Does not convey the equivalent registration.

- For example, coincident distribution does not grant you a distribution registration

Registration should reflect primary activity

EXAMPLE SCENARIO ONE:

Manufacturer "A" manufactures dosage units for a clinical trial (schedule II)

1. Can they conduct the clinical trial under their manufacturer registration?

   Yes, because research is a coincident activity to their primary activity (manufacturing) under their manufacturing registration

EXAMPLE SCENARIO CONTINUED:

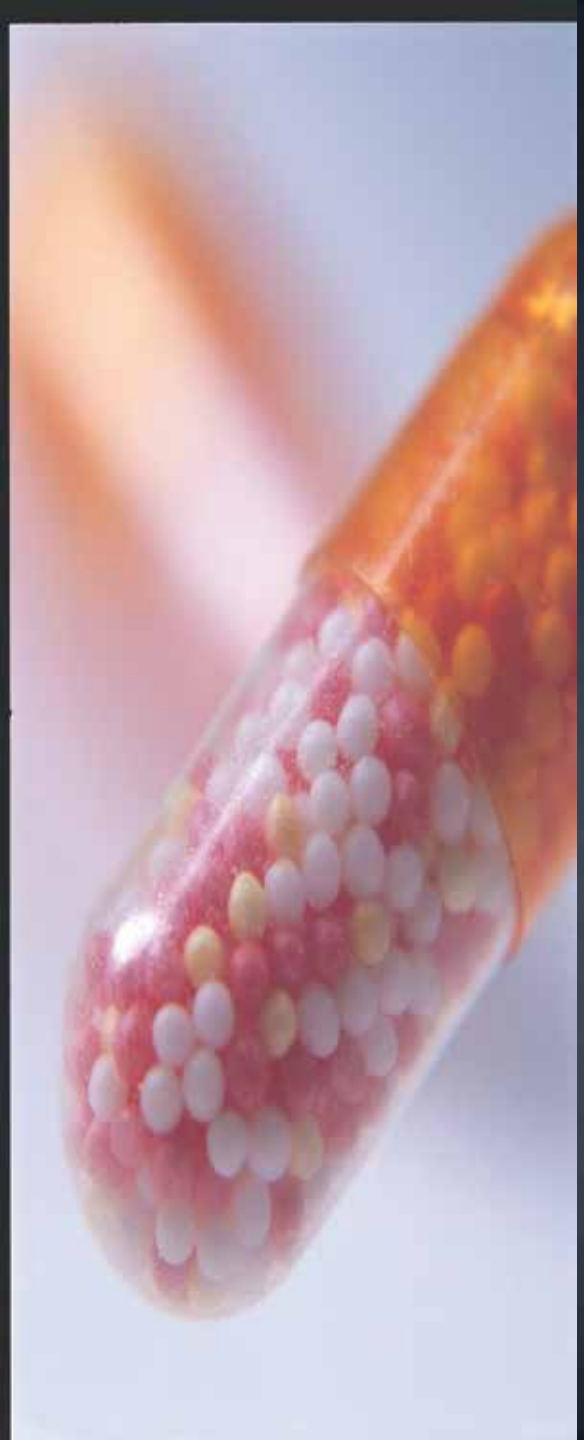
2. Can they distribute the material to a second manufacturer (Manufacturer "B") to conduct the clinical trial?

- ü Yes, they may distribute as a coincident activity
- ü The second manufacturer ("B") is required to have adequate procurement quota to receive the material
- ü However, the second manufacturer ("B") can not conduct research on the material. Since they did not manufacture the dosage units, they may not conduct a coincidental activity, i.e. research, with it

EXAMPLE SCENARIO ONE CONTINUED:

3. Can they distribute the material to a research registration to conduct the clinical trial?

Yes, they may distribute the material as a coincidental activity because research is the primary activity of a Research registration, therefore, the researcher may perform research on the received material

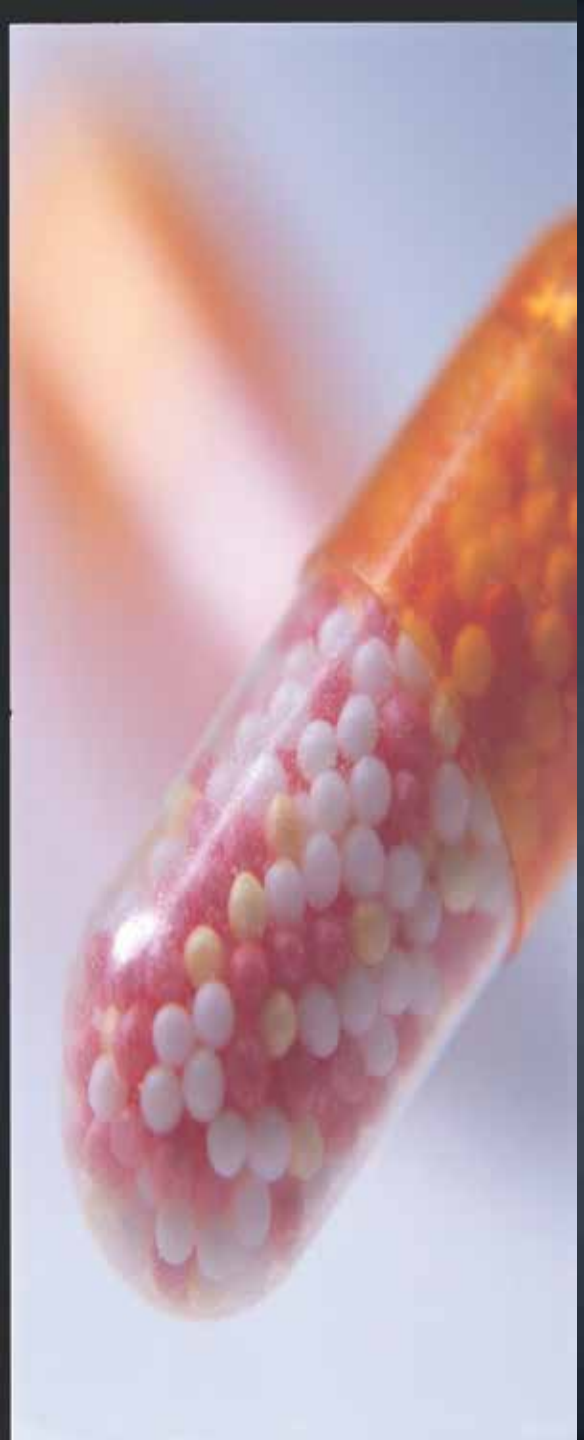


EXAMPLE SCENARIO TWO:

Manufacturer “A” manufactures dosage units (schedule II) for distribution.

1. Can they ship the material to their sister manufacturer registration (Manufacturer “B”)?

   Yes, distribution is coincident to their primary activity, i.e. manufacturing. Therefore they may distribute the manufactured material.



EXAMPLE SCENARIO TWO CONTINUED:

Can the second Manufacturer "B"

1. Distribute the material?
2. Conduct research?
3. Perform analysis?

No. Since this facility did not manufacture the material, they may not perform coincidental activities on it.

Manufacturer "B" would have to perform a manufacturing activity before they can conduct a coincidental activity

WHO TO ASK FOR DETERMINATIONS

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Diversion Control Division/DRQ
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QUESTIONS?

U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control