



Unwanted Product Material: Pharmaceuticals and Other Headaches

**Barton Day
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Unwanted Product Material

- Unused product outside its normal pattern of distribution/use
 - Off-spec/expired product
 - Damaged product/packaging
 - Returned product
 - Excess product
- May be in hands of manufacturer, distributor, retailer or end user

Primary Issues

- Is the material RCRA hazardous waste?
- Are there other legal constraints on its disposition?
 - FIFRA
 - Controlled Substances Act
 - Other
- Policy/potential liability

RCRA Waste Determination

- Required for all solid waste (40 C.F.R. 262.11)
- Commercial chemical product listings (“P” and “U” lists)
- Hazardous characteristics
 - Ignitability, corrosivity and reactivity
 - The toxicity characteristic
- Beware reliance on MSDSs

Hazardous Waste

- Must generally be managed as such
- Key exceptions:
 - Product taken back from consumers (and segregated from other hazardous waste) is household hazardous waste
 - Waste from conditionally-exempt small quantity generators (and segregated from other hazardous waste) is subject to very limited regulation.

Policy/Liability Issues

- Can you confirm/consistently maintain CESQG status?
- Can you reasonably avoid commingling household or CESQG waste from other hazardous waste?
- Would you be comfortable throwing hazardous waste in the trash even if it were clear that you could?

Solid Waste Determination

- Product material is not solid waste if used:
 - “As is” (no processing of any kind) AND
 - for its originally intended purpose
 - But beware FIFRA labeling requirements
- Otherwise RCRA recycling rules apply
- Material being recycled IS solid waste unless a recycling exclusion applies

Key Recycling Exclusions

- Product material is not solid waste if “reclaimed”
 - Processed to recover useful product
 - or regenerated
- Used without prior reclamation as:
 - A substitute for a commercial product
 - A raw material to produce a product
- Recycling must be “legitimate”

Key Exceptions to Exclusions

- “Use constituting disposal” – material generally is solid waste if:
 - Used by being put on the ground
 - Used to produce a product that is put on the ground
- Material generally is solid waste if used as fuel or to produce fuel

When is Product Waste?

- Not as long as there is a reasonable belief that it can be used (for original purpose) or recycled pursuant to an exclusion
- There is no specific deadline (the “speculative accumulation” rule does not apply to product material)
- But be reasonable

Being Reasonable = Consider:

- The circumstances involved (why is there an issue about the material?)
- The nature and condition of the material
- The pattern of disposition for similar material
- Important: consider each product material separately

Reverse Distribution

- Product is not solid waste if:
 - There is a legitimate question as to whether the material can be recycled or resold; and
 - The manufacturer is taking the material back to make that determination
- In this scenario the manufacturer is the generator of any material ultimately discarded

Reverse Distribution (Cont'd)

- Pharmaceutical products may be sent to reverse-distributors to arrange for manufacturer credit
- Product may not be solid waste even if clearly destined for disposal (?)
- The reverse-distributor is the “generator” for any material not returned to manufacturers

Other Pharmaceutical Issues

- Controlled substances can only be sent between DEA registrants
- DEA registrants can send to:
 - DEA registered reverse-distributor
 - DEA registered RCRA-permitted facility
- Non-DEA registrants must generally destroy controlled substances

Pharmaceutical Issues (Cont'd)

- HIPAA privacy requirement: can't send products off-site until any patient information has been removed or obscured
- State law requirements (various)
- Unique risks associated with pharmaceuticals