

Who Should Not Register or List

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OC | CDER | US FDA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct
SBIA 2024 Workshop



Learning Objectives



- Provide registration and listing exemptions
- Explain the legal status conferred by registration and listing
- Describe the implications of incorrect submissions

Registration and Listing Exemptions



- Described under 21 CFR 207.13
 - Pharmacies
 - Hospitals, clinics, health care entities, and public health agencies
 - Manufacturers of drugs solely for use in research, teaching, or chemical analysis and not for sale
 - Manufacturers of harmless inactive ingredients
 - Practitioners who are licensed by law to prescribe or administer drugs
 - Establishments under contract engaged solely in recovering cells or tissues and sending to the registered establishment

What They All Have in Common



- They do not engage in the manufacture, repackaging, relabeling, or salvaging of any drug
- The drug they manufacture does not enter U.S. commercial distribution

Why Companies May Incorrectly Register and List



- Some companies may use FDA registration and listing or their appearing in FDA databases to falsely represent that FDA has stated their product is legal or approved.
- Some companies may want a product to appear as a drug in certain publications when it is not a drug.

Don't!

It may be illegal

Registration and Listing – Legal Status



- Under 21 CFR 207.77(a) and 207.77(b), registering an establishment or listing a drug, FDA's acceptance of registration and listing information, inclusion of a drug in the FDA database, or assignment of an NDC does not denote approval of the:
 - Establishment
 - Drug or other drugs of the establishment
 - Legal marketing of the product

And



- “Neither registration nor listing constitutes a determination by FDA that a product is a drug as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.
- Registration or listing may, however, be evidence that a facility intends to or does manufacture, repack, relabel, distribute, or salvage drugs or that a product is intended to be a drug.” (21 CFR 207.77(c))

Misleading Labeling

- “Any representation that creates the impression that a drug is approved or is legally marketable because it appears in our database of drugs, has been assigned or displays an NDC, or the establishment has been assigned an establishment registration number or Unique Facility Identifier is misleading and constitutes misbranding.” (21 CFR 207.77)

You Should Not



- Use FDA logo
- Use the term FDA-registered to denote legitimacy or approval by FDA
- Include the term FDA-approved for a product that is not subject to FDA review and approval, or is not approved by FDA

Implications of Incorrect Submission



- You may be assessed and subject to other requirements such as:
 - User fees dues
 - FDA inspections
 - CGMP requirements
 - Drug amount reporting requirements

Challenge Question # 1

You should list your drug product intended for use in clinical trials and not for sale.

- a. True
- b. False

Challenge Question # 2

You should register your establishment even though your drug(s) are not imported or offered for import into U.S.

- a. True
- b. False

Challenge Question # 3

A registered establishment is subject to FDA inspection.

- a. True
- b. False

Resources



- <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls>

In Summary



- Products that are not drugs:

SHOULD NOT BE LISTED

- Facilities that do not manufacture or process drugs:

SHOULD NOT BE REGISTERED

Questions?

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