

# Complying with Establishment Registration Requirements

**Tasneem Hussain Pharm. D**

Pharmacist, Consumer Safety Officer

Division of Labeling, Registration, and Unapproved Drugs

Office of Unapproved Drugs & Labeling Compliance

OC | CDER | US FDA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct

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# Learning Objectives



- Describe the establishment registration requirements under 21 CFR 207
- Identify some common registration related issues
- Explain the compliance program and deficiency letter highlights
- Describe effects of non-compliance

# Establishment Registration Requirements



- Section 510 of FD&C Act 21 U.S.C. 360(b) (c), (d) and (i)
- 21 CFR 207 Subpart B
  - 207.17- Who Must Register?
    - All domestic and foreign manufacturers



# Establishment Registration Requirements



- 207.21- When to submit the initial information
  - Domestic manufacturers - no later than 5 calendar days after manufacturing starts
  - Foreign manufacturers- must do it **before** importation

# Establishment Registration Requirements



- 207.25 - What information to include
  - Name of owner or operator of each establishment
  - Name(s) of establishment, physical address, phone, contact info
  - Registration number, Unique Facility Identifier
  - Business operation(s)
  - Name and address of official contact for establishment

# Establishment Registration Requirements



- 207.25 continued

For foreign establishments:



- Name and address, telephone, and email for
  - US Agent – more under 207.69(b)
  - Each importer in U.S.
  - Each person who imports or offers for import

# Registration Update Requirements



- 207.29 - Requirements for updating registration information
  - Closing or selling of establishment
  - Changes to establishment name or address
  - Any change made to official contact or U.S. agent information
  - Renew / update between Oct.1 to Dec.31 annually

# Where is Registration Data found

- Drug Establishment Current Registration Site (DECERS)
  - FDA's online registration database
  - If firm properly registers with FDA – data is here
- Establishment data is removed from this site if:
  - Deregistered
  - Registration has expired
  - Registration data is inactivated due to compliance case



# Common Registration Issues



- Facility SHOULD NOT register
- DUNS issues or Missing FEI
- Incorrect or incomplete business operations or operation qualifiers
- Unauthorized U.S. agent
- Unauthorized submissions
- Outdated contact information



# Compliance Program



- Started in 2015
- Mission: to protect and promote public health by striving to achieve accuracy and integrity of establishment registration and drug listing data
- Phases of compliance actions
  - Review of data
  - Deficiency letter
  - Data removal
  - Further actions – registration data is inactivated, warning letter



# Compliance Program

## Deficiency Letter Highlights

- Statement of deficiency in 1<sup>st</sup> paragraph
- 30 days for corrections
- **Non-delivery of letter does not stop the process**
  - Requirement to update registrant contact info under 21 CFR 207.29(a)(3)
- Instructions for submitting corrections

# Importance of Registration



- An inventory of all drug manufacturers who are producing drugs for sale in the U.S.
- Aids in inspection program
- Assists in drug shortage cases
- Post-market surveillance and adverse event reports
- Required for drug import and export

# Effects of Non-Compliance



- Outdated contacts – Registrant and establishment will not receive timely FDA communications and notifications
- DUNS issues can create validation errors
- Incorrect or incomplete data can lead to compliance cases
- Unresolved compliance case – registration data removal from DECERS

# Effects of Non-Compliance



- Misbranding - section 502(o) of FD&C Act
  - Introduction or delivery of a misbranded drug in interstate commerce is prohibited - section 301(a) FD&C Act, U.S.C. 331(a)
- Importation issues- section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3))
- Warning letters

# Challenge Question #1



Under which 21 CFR 207 subpart are the registration requirements found?

- A. Subpart A
- B. Subpart B
- C. Subpart C
- D. Subpart D

# Challenge Question #2



All the following are true about establishment registration requirements except:

- A. Establishment registration must be updated annually between October 1 and December 31
- B. Foreign establishments must register initially within 5 days of beginning to manufacture
- C. Foreign manufacturers must include US agent and importer information
- D. A “No Changes” notification SPL may be used to renew the registration



# Challenge Question #3



What are some negative effects of not complying with registration requirements

- A. Firm may receive a deficiency letter
- B. Data may be removed from DECERS
- C. Inclusion of an incorrect or expired manufacturer may lead to misbranding charges for the listed drug
- D. All the above

# Summary



- Review and follow the registration requirements to maintain compliance
- Compliance program aims to keep data submitted to FDA accurate and complete
- Establishment registration must remain current as this can affect drug listing data
- Failure to comply can lead to some negative effects

# Closing Thought

Complying can be EASY  
IF YOU FOLLOW REGULATIONS  
and  
Submit CORRECTLY the FIRST TIME

# Resources



- Electronic Code of Federal Regulations : 21 CFR Part 207:
- <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207>
- Drug Establishment Current Registration Site:
- <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site>
- Electronic Registration and Listing Compliance Program | FDA:
- <https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-registration-and-listing-compliance-program>



# Questions?

[eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov)

