Complying with Establishment Registration Requirements

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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 (DECRS)
  - 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- Outdated contact information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 1st 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 DECRS

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 DECRS

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

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Questions?

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