

### Listing Updates and Delisting

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#### Overview



- Who must update drug listings and when?
- What information must be submitted when updating drug listing information?
- Who must delist a product and when?
- How to delist and update drug listing information using CDER Direct?
- Challenge Question

### **Learning Objectives**



Describe the drug listing requirements

Identify who needs to update drug listing and when

Identify who needs to delist and when



#### Who must update drug listings and when?

 Under 21 CFR 207.57(b), each registrant must review and update their drug listing information no later than June and December of each year.

 Under 21 CFR 207.57(c), registrants are encouraged to update listing information at the time of any change affecting information previously submitted.



# What information must be submitted when updating drug listing information?

- Under 21 CFR 207.57, provide drug listing information for any drug manufactured, repacked, relabeled, or salvaged that has not been previously submitted.
- Submit the date an establishment discontinued the manufacture, repacking, relabeling or salvaging of a listed drug and provide the expiration date of the last lot manufactured, repacked, relabeled or salvaged.
- Submit any material changes to any information previously submitted.
- Submit the date an establishment resumed the manufacturing, repacking, or relabeling a drug previously discontinued.



### Who must delist a product and when?

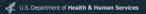
- Under 21 CFR 207.57(b)(2), each registrant must delist their products when the product is no longer in U.S. commercial distribution.
  - ➤ For foreign manufacturers, importation is commercial distribution.

 Submit the drug's marketing end date. This date should be the expiration date of the last lot manufactured or distributed.



## How to delist and update drug listing information CDER Direct Live Demo

https://direct.fda.gov/





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### Challenge Question!!



## How often must a registrant review and update their drug listing information?

- a. Once a year
- b. Every month
- c. Never
- d. June and December each year



#### Thank You!

Contact us: eDRLS@fda.hhs.gov

