

# Establishment De-Registration

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Electronic Drug Registration and Listing Using CDER DIRECT

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# Overview

- Why is De-Registration Important?
- When to De-Register?
- What are the De-Registration SPL Document Types?
- What to do after De-Registration?
- Demonstration in CDER Direct
- Challenge Question

# Why is De-Registration Important?



- Preserve integrity and accuracy of the system when establishments are no longer manufacturing drugs
- Assists the agency in conducting mission critical activities
  - Database is relied upon for many programs
    - Internal – Inspection planning, Post marketing surveillance, Recalls, Monitoring drug shortages, etc.
    - External – Reimbursement, Prescribing, Supply Chain
- Alerts business partners when there are changes

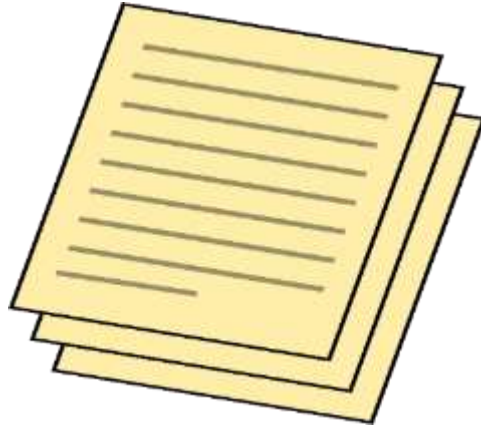


# When to De-Register?

- Annual registration renewal period: Oct-Dec
- 21 CFR 207.29 states that expedited registration updates to be provided within 30 calendar days of a change
  - Closing or selling of an establishment when no longer manufacturing drug products

# What are the SPL Documents to De-Register Establishments?

- Establishment De-Registration SPL
- Out of Business Notification SPL



# Establishment De-Registration SPL



- De-Register if the establishment(s) is/are no longer manufacturing drug products for commercial distribution in the US
- May still manufacture non-drug products
  - Check possible registration requirements with other FDA centers



# Out of Business Notification SPL



- Firm/establishment is no longer in business



# Multiple Establishments

- Multiple establishments on one Registration SPL:
  - Establishment De-Registration or Out of Business Notification SPL will de-register all establishments.
  - To de-register one or any fewer than all establishments, drop the de-registered establishment(s) in a new version of the SPL.



# What to do after De-Registration?




- Drug listing updates
  - All affected listing SPLs must be revised
  - Discontinued, if no longer manufactured
    - Enter **future** end marketing date to allow for existing supply to be exhausted
  - Updated to include a new manufacturing establishment, if drug remains in the market
- Labeler code updates
  - If an establishment no longer manufactures drugs or goes out of business, labeler code should be inactivated


<https://direct.fda.gov>


# **DEMO of CDER Direct**

# De-Registration Demonstration

 U.S. Department of Health & Human Services

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STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
<a href="#">SUBMISSION ACCEPTED</a>	ca643b2-7c35-8131-e053-2a95af0a3854	ca639dd3-8445-c128-e053-2a95af0a804e	cd4865173209.7824501593@direct	3	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 13:51:09	
<a href="#">SUBMISSION ACCEPTED</a>	ca5028b4-e845-0b05-e053-2a95af0a812a	caff1dc3-3438-1485-e053-2a95af0a03d1	cd6253017498.9436017825@direct	3	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 11:45:12	
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<a href="#">SUBMISSION ACCEPTED</a>	ca5028b4-e845-0b05-e053-2a95af0a812a	ca5028b4-e846-0b05-e053-2a95af0a812a	cd1480697532.3674218905@direct	1	ESTABLISHMENT REGISTRATION	Vikas Arora	26-AUG-2021 09:56:49	

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# De-Registration Demonstration (cont'd)



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GO ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
<a href="#">SUBMISSION ACCEPTED</a>	ca643fb2-7c35-8131-e053-2995af0a3854	ca039dd3-8447-e128-e053-2995af0a804e	cd347168529.9042763150@direct	4	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 14:01:10	
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<a href="#">SUBMISSION ACCEPTED</a>	ca5028b4-e045-0b05-e053-2a95af0a82a	ca01dcd3-3438-14f5-e053-2a95af0ad3d1	cd6253017498.9436017825@direct	3	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 11:45:12	
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# Challenge Question

**A manufacturing establishment which was manufacturing hand sanitizers in response to the pandemic, stops production. Within how many days should it De-Register with FDA?**

- A. Same day
- B. 14 days
- C. 30 days
- D. Between October and December



# Summary

- De-register in a timely manner!
  - Simple and quick process
  - Alerts the agency and others of the removal of establishment(s) and change in business status
- Report all required updates to FDA
  - Establishment De-Registration vs. Out of Business Notification
  - Drug listing
  - Labeler code

# Thank You for De-Registering!

**Contact Us:**

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

