

Who Will Be Assigned a Labeler Code and Who Won't

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CDER | US FDA

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Learning Objectives



After participating in this session, attendees should be able to:

- Define each segment of a Labeler Code
- Describe when a Labeler Code must be requested
- Explain the situations for who needs to apply

What

- NDC is 3 segments:
 - Labeler Code, Product Code, Package Code
- Labeler Code assigned by FDA
- Product and Package codes proposed by labeler



When

- Must submit prior to listing
- If no drugs to list, do not apply
- Labeler codes without listed NDCs **INACTIVATED** after 24 months



Who

- 21 CFR Part 207
 - All registrants who must list
 - All PLDs whose drugs must be listed
- Labeler codes are assigned to companies
 - Not site specific
 - Sites under common ownership can share
- DUNS are site-specific



Rejections

- Not required to register or list
 - Product is not a drug
 - Not a manufacturer or PLD for the drug
- Already have labeler code assigned
- Labeler code was inactivated



Rejections

- Does not match Dun and Bradstreet data
- Veterinarian drug manufacturer or distributor
 - Submit NDC Labeler Code Request-Animal Drug (LOINC Code-72871-7) to CVM



Challenge Question 1



If a company has three establishments under the same ownership, how many labeler codes do they need?

- a) One labeler code
- b) Two labeler codes
- c) Three labeler codes (one for each site)

Challenge Question 2



Application holders/sponsors that perform no manufacturing process must be assigned a labeler code:

- a) No, entities that do not manufacture any drugs, should not be assigned a labeler code
- b) Yes, all applicants must be assigned a labeler code
- c) It depends. If an applicant is also the PLD, then a labeler code must be assigned



Resources

- [Electronic Drug Registration and Listing Instructions | FDA](#)
- **Contact Us:** eDRLS@fda.hhs.gov



Summary

- NDC has 3 segments
- If no drugs to list don't apply
- Labeler code inactivation
- Labeler code is company-specific

Questions?

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Closing Thought

With the information and resources for the What, When and Who, you can now more confidently request a labeler code.



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