

Establishment Registration: Top Do's and Don'ts

Regie Samuel

Technical Information Specialist

OC/OPRO/DRLS

CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT

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Top 5 Do's



- 1) Update your firm's information with Dun and Bradstreet before submitting an Establishment Registration
- 2) Ensure that the Establishment information you enter (company name and address) *exactly* matches what is in the DUNS record
- 3) Ensure that all email addresses (and phone numbers) are valid and accurate as future FDA correspondence will be sent to the email contact addresses provided



Top 5 Do's

- 4) Use “Create New Version” to edit your SPL if your Establishment Registration SPL is grayed out and you are unable to edit a field
- 5) Verify Registration: Check the Drug Establishments Current Registration Site (DECRS) 1-2 business days after submitting registration
- 6) Click the “Submit SPL” button to send the SPL to the FDA



Top 5 Don'ts

- 1) Do *not* use the business operation of “Label” if you are a private label distributor
- 2) Do *not* register as a drug establishment via an Establishment Registration SPL, if your firm is solely a Private Label Distributor
- 3) Do *not* register a firm you if do not have authorization to register it

Top 5 Don'ts



- 4) Do *not* submit an Establishment De-Registration SPL if you only want to de-register some, but not all, of the Establishments associated with that registration
- 5) Do *not* request FEI's via eDRLS@fda.hhs.gov. If an FEI number has been assigned, the FEI Search Portal can be accessed to find the FEI number assigned to a site in question at:

<https://www.accessdata.fda.gov/scripts/feiportal>

Challenge Question #1

Who should not register as a drug establishment?

- A. Repackagers
- B. Contract Manufacturers
- C. Private Label Distributors
- D. Manufacturers

Thank You!

Contact Us:

eDRLS@fda.hhs.gov