SPL Quick Reference eCard
Newer or Revised Validation Procedures (Common Errors)
Content of Labeling/Product Data Elements SPL Documents

Error Message/Comment	Solution
Act definition code matches code for an establishment with same id previously submitted in documents of type "establishment registration" in the same or previous calendar year	- Ensure that the DUNS Number for the drug establishment is correct. - Ensure that the type(s) of operation for each establishment is correct. - Ensure that the drug establishment has been registered this calendar year or at least the previous calendar year.
If the NDC product/item code was previously submitted, then the product and generic name, source, active ingredient UNII, dosage form, active ingredient strength, product characteristics of size, shape, color and imprint code are the same as in the most recent submission for this NDC product/item code.	- Ensure that the product information is the same in this subsequent submission. - If you are correcting an error or if you believe that the information you entered is correct, send an e-mail to spl@fda.hhs.gov with the **core ID** of the submission to request a manual override. If your request is granted, the file will be manually loaded. You will **ONLY** be notified via e-mail regarding your manual override request if your request is **NOT** granted.
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA) and the application number was already submitted, then the active ingredient UNIIs are the same as in any previous submission of a product with the same application number.	If the product is associated with the marketing categories "ANDA," "BLA," or "NDA," and the application number has been included in a previous SPL submission, the active ingredients' UNIIs have to be the same as those in any previous submission of an SPL for a product with the same application number.
id does not match any other id across all sections, documents, or any id other than the id of the same section previously submitted	If you change the content of a section, the section root ID has to be changed.
If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits	If the product is regulated by CDER as an ANDA, the six-digit application number should be preceded by "ANDA." If the product is regulated by CBER as an ANDA, the six-digit application number should be preceded by "BA"
If the code is C73594 (NDA) or C73605 NDA authorized generic), then the id extension has the prefix "NDA" or "BN" followed by 6 digits	If the product is regulated by CDER as an NDA or NDA authorized generic, the six-digit application number should be preceded by "NDA"

	If the product is regulated by CBER as an NDA, the six-digit application number should be preceded by “BN”
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA), then there exists a record of an application for the application number.	If the application number is associated with an ANDA, BLA, or NDA, that application number exists in the FDA’s application number database.
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA) and the marketing is active with a start date on or before the current date, then there exists a record of an approved application for the application number.	If the application number is associated with an ANDA, BLA, or NDA, the marketing status is “active” and the marketing start date is on or precedes the current date, there is a record of an approved application for that application number in the FDA’s application number database.
If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA) and the marketing status is completed, then there exists a record of an approved or withdrawn application for the application number.	If the application number is associated with an ANDA, BLA, or NDA and the marketing status is “completed” then there is a record of an approved or withdrawn application for that application number in the FDA’s application number database.
If document type is 60684-8 (Cellular Therapy), 60683-0 (Plasma Derivative) and 53404-0 (Vaccine Label), then there is a package item code with code and code system for the inner, unit of use package.	If the document type is Cellular Therapy, Plasma Derivative, or Vaccine Label, then there is a package item code (NDC package code) for the inner, unit of use package.
If active ingredient code are on the list of active ingredients approved for vaccines, then the document type code is 53404-0 (Vaccine Label).	If an active ingredient UNII is on the list of active ingredients approved for vaccines, then the document type code is Vaccine Label.
If the document type code is 53404-0 (Vaccine Label), then there must be at least one active ingredient code on the list of active ingredients approved for vaccines.	If the document type is Vaccine Label, then there must be at least one active ingredient UNII on the list of active ingredients approved for vaccines.
If the code is C92556 (Legally Marketed Unapproved New Animal Drugs for Minor Species), then the id extension has the prefix “MIF” followed by 6 digits.	If the marketing category is Legally Marketed Unapproved New Animal Drugs for Minor Species then the application number has the prefix “MIF” followed by 6 digits.
If any of the products without a marketing completion date in a Prescription Animal Drug (50578-4), OTC Animal Drug (50577-6) or Animal Medicated Article or Medicated Feed (50576-8, 50574-3, 50573-5, 50575-0, 50572-7, 50571-9) listing has no product source, then establishments with operation of API manufacture	If any of the products without a marketing completion date in a Prescription Animal Drug, OTC Animal Drug, or Animal Medicated Article or Medicated Feed SPL has no product source, then an establishment with the business operation of API manufacture (C82401) is included.

(C82401) are included.	
If the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C), then there is no operation-product link.	If the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B, VFD type C, then there is no establishment-product relationship link.
If the marketing category is C95600 (Approved drug product manufactured exclusively for private label distributor), then there is an id.	If the marketing category is Approved drug product manufactured exclusively for private label distributor then there is an application number.
If the marketing category is C95600 (Approved drug product manufactured exclusively for private label distributor), C95601 (OTC monograph drug product manufactured exclusively for private label distributor), C95602 (Unapproved drug product manufactured exclusively for private label distributor), then the document type must be 34391-3 (Human prescription drug label) or 34390-5 (Human OTC drug label)	If the marketing category is Approved drug product manufactured exclusively for private label distributor, OTC monograph drug product manufactured exclusively for private label distributor, Unapproved drug product manufactured exclusively for private label distributor then the document type must be Human prescription drug label or Human OTC drug label.
If any of the products without a marketing completion date in this listing has no product source, then at least one establishment with a manufacture operation is included such as API manufacture (C82401), manufacture (C43360), or positron emission tomography drug production (C91403)	- If the products described in the SPL file are currently marketed and has no product source (source NDC product code) then an establishment with the following business operations is included: "manufacture," "API manufacture," or "positron emission tomography drug production. If the products described in the SPL file all have a marketing end date (discontinued marketing) then no establishment data elements are needed (remove coding for the establishment data elements as well.