

Establishment Registration SPL Technical Errors Training eBook

Interpretations & Solutions for
Technical Errors in Establishment Registration SPL Documents
Submitted to FDA

Version 1.0

Purpose:

This SPL training eBook is to be utilized by SPL document authors as a reference to determine the source of and locate the solution for technical errors in Establishment Registration SPL documents submitted to FDA. This is a “living” document. More content will be included as SPL validation procedures are added or refined.

How do you know when you have received an error message?

A second or third acknowledgment indicates that there is an error in your submission. At the time of the publication of this eBook, error messages (second or third acknowledgments) are transmitted within 24 – 48 hours (business days) of FDA’s receipt of your submission.

Technical Terms Glossary

Term	Definition
Core ID	A unique identifier which the FDA Electronic Secure Gateway (ESG) (e.g. WebTrader) assigns to every submission. This core ID should be used to refer to your Gateway SPL submission.
Document Root ID	Globally Unique Identifier (GUID) and is unique for each version of an SPL document document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	Provides a date reference to the SPL document version or a section including the year, month and day as yyyyymmdd.
GUID	Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
Hyperlink ID	Used to cross reference sections in content of labeling. Allows reader of document to navigate to the cross referenced sections (Not used in
Observation Media ID	Identifier for the image file (doesn't have to be a GUID)
Product data elements	The structured data about your product(s) (e.g. proprietary name, dosage form, route of administration, package description) (Table at the rendered near the end of the SPL document)
Section ID	GUID which is used to identify a section
SetID	GUID which is a unique identifier for the document that remains constant through all versions/revisions of the document.
UNII	Unique Ingredient Identifier (UNII) is a non- proprietary, free, unique, unambiguous, non semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.
UUID	Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	Integer greater than zero that provides a sequence to the versions of the document.

Document Tracking Information

Document Tracking Information	
This section includes some of the error messages and solutions for document tracking information in Establishment Registration SPL files.	
Error	Solution
There is an id	Include a document root ID (GUID)
SPL file name must be the id root followed by ".xml"	Name the file with the document root ID. (Do not use creative names for the file name.) Include “.xml” after the document root ID
A submission contains only the SPL file whose name ends in '.xml' and associated image files whose names end in '.jpg'.	Remove any non-SPL files from the folder. Ensure the file extension (e.g. .xml (lower case letters) is included.
There is an effective time with at least the precision of day in the format YYYYMMDD	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20131221 for December 21, 2013)
The value " of attribute 'value' on element 'effectiveTime' is not valid with respect to its type, 'ts'.	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20131221 for December 21, 2013)
id must be unique across all documents	Change the document root ID (GUID) to a GUID that is not in FDA system.
" is not a valid value of union type 'uid'.	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in ID field.
The value " of attribute 'root' on element 'id' is not valid with respect to its type, 'uid'.	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in ID field.
id root must be a Globally Unique Identifier (GUID).	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in (document) ID field.
id does not have an extension.	Do not include an extension for the ID (this is a coding extension)
id does not match any other id in the document.	Use each GUID one time and one time only.
id is unique across all documents, sections and any other ids	Use each document root ID one time and one time only – do not use that same document root ID in subsequent submissions
There is an id Include a document root ID (GUID) setId must be a GUID	Generate a setId using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setId field.

Document Tracking Information

This section includes some of the error messages and solutions for document tracking information in Establishment Registration SPL files.

Error	Solution
The value " of attribute 'root' on element 'setId' is not valid with respect to its type, 'uid'.	Generate a setID using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setID field.
Value of version number must be a whole number > 0	Enter a version number which is a whole number that is greater than "0"
" is not a valid value for 'integer'.	Use a whole number in the version number field.
The value " of attribute 'value' on element 'versionNumber' is not valid with respect to its type, 'int'.	Use a whole number in the version number field.
Value of version number must be greater than the value of any previously submitted version for the same setId	Increase the document version number by one whole number.
There is an id Include a document root ID (GUID) setId must be a GUID	Generate a setID using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setID field.

Establishment Registration SPL

Determine the source of and locate the solution for the errors in one's Establishment Registration SPL document in the list below.

Error/Comment	Solution
<p>The DUNS number along with the establishment name and address information match the DUNS number record in the Dun and Bradstreet database</p>	<p>The name, address, and DUNS Number for each drug establishment should match information in the D&B DUNS Number database.</p> <p>If you believe that the information you have 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 it appears that there is a discrepancy in the D&B DUNS Number database, the file will be manually loaded. If the file is manually loaded, you may check the Drug Establishment Current Registration Status website (http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm) within one to two business days for the update. You will ONLY be notified via e-mail in response to your manual override request e-mail if your request is NOT granted.</p>
<p>DUNS number is not associated with any other set id for document type "Establishment registration"</p>	<ul style="list-style-type: none"> - The establishment's DUNS Number can only be simultaneously included (linked to one setID) in one establishment registration SPL file at a time. - Use the original set ID for the establishment registration SPL file. - In case of mergers/acquisitions - If you need to transfer the information about drug establishment(s) from one establishment registration SPL file to another, the previously submitted establishment registration SPL file with the information about the drug establishment should be updated to remove the data about the transferred drug establishment. If there is only one establishment identified in the previously submitted Establishment Registration SPL file, use the Establishment De-Registration or Out of Business Notification SPL file to disassociate the information about the drug establishment from the previous owner/operator (registrant.) The revised file, the Establishment De-Registration, or Out of Business Notification SPL file should be submitted prior to the submission of the establishment registration SPL document which now links the new owner/operator (registrant) to the newly acquired drug establishment.

Establishment Registration SPL

Determine the source of and locate the solution for the errors in one's Establishment Registration SPL document in the list below.

Error/Comment	Solution
id must not be associated with any other set id for document type "Establishment registration"	DUNS Number for registrant is associated with only one Establishment Registration SPL document's setID. Include all of the drug establishments owned/operated by registrant in one Establishment Registration SPL document. If you have already submitted to FDA an SPL as a test or official submission, use the setID of that original Establishment Registration SPL document.
set id is not associated with any other id	A set ID can only be associated with one registrant's DUNS Number. If you have to change the registrant's DUNS Number, you will need to submit an Out of Business Notification SPL file or Establishment De-Registration SPL document and then, on this rare occasion change the set ID of your Establishment Registration SPL file which has the new registrant's DUNS Number. Submit the Out of Business Notification or Establishment De-Registration SPL file prior to the submission of the "new" Establishment Registration SPL document.
There is one contact party	Include the contact information for the registrant. Do not enter information for more than one contact party. Please review solutions in the "Contact & Address" information section of this document.
The id is not associated with another establishment in the same SPL file.	Do not use the same DUNS Number for more than one drug establishment in your file. DUNS Numbers are site-specific. Obtain the other location's DUNS Number from D&B. If D&B will absolutely only assign one DUNS Number because the sites are located on the same campus , at the time of the publication of this eBook, you should enter information for one of the drug establishments.
If the document type is "establishment registration", then there are one or more establishments.	An Establishment Registration with the document type "Establishment Registration" should have information for one or more drug establishments.
If there is a second id element, then its root is 2.16.840.1.113883.4.82 and the extension is 7 or 10 digits	In this instance, the "id element" is the FEI number. If you have an FEI number enter it. If not, delete the FEI number field. Enter SEVEN- or TEN- digit FEI numbers. If necessary, include leading zeros for older FEI numbers (e.g. 0001444)

Establishment Registration SPL

Determine the source of and locate the solution for the errors in one's Establishment Registration SPL document in the list below.	
Error/Comment	Solution
There is one name	There is one name for each drug establishment .
Each establishment has an address	Include an address for each drug establishment . (See the solutions for address errors in the "Contact & Address" information section of this document.)
The code comes from the business operations list except for C73599 (import) and C73330 (united states agent)	Add a type of operation; however, DO NOT add "import" or "united states agent" as a type of operation for an establishment. Include "import" or "united states agent" in the Importer or United States Agent fields – NOT as the type of operation for a drug establishment
There are one or more establishment operation details (performance act definitions).	Include one or more types of operation for each drug establishment. Those types of operations (for this field) can NOT be "United States Agent" or "Importer."
There is no assigned entity other than for US Agent or Import business.	In the US agent and Import fields, only include the "United States Agent" and "Import"
If the country for the establishment is not "USA", then there is one US agent	Foreign drug establishment registrants should include information (US agent's company name, DUNS Number, telephone number, and e-mail address) for ONE US agent.
If the country for the establishment is "USA", then there is no US agent	Do not include US agent information for drug establishments located in the USA.
There is one id (US agent)	Include a 9-digit DUNS Number (without hyphens) for the US agent.
id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension (US agent)	Include a 9-digit DUNS Number (without hyphens) for the US agent.
There is one name (US agent)	Include the name (company name) for the US agent.
There are two or more telecom elements	Include the telephone number and e-mail address for the US agent. (see "Contact & Address" information section of this document for solutions)
There is one contact party	Include the contact information for the drug establishment (See the solutions for "Contact & Address" information section of this document.)

Establishment Registration SPL

Determine the source of and locate the solution for the errors in one's Establishment Registration SPL document in the list below.	
Error/Comment	Solution
The code comes from the business operations list except for C73599 (import) and C73330 (united states agent)	Add a type of operation; however, DO NOT add “import” or “united states agent” as a type of operation for an establishment. Include “import” or “united states agent” in the Importer or United States Agent fields – NOT as the type of operation for a drug establishment
If the country code for the establishment is not USA, then there may be one or more import businesses.	If the drug establishment is NOT located in the USA then there MAY be one or more importers.
If the country code for the establishment is USA, then there are no import businesses	If the drug establishment is located in the USA then there should NOT be any importers related to this drug establishment.
There is one id (Importer)	Do not include import information for drug establishments located in the USA.
If the country code for the establishment is not USA, then there may be one or more import businesses.	If the drug establishment is NOT located in the USA then there MAY be one or more importers.
If the country code for the establishment is not USA, then there may be one or more import businesses.	If the drug establishment is NOT located in the USA then there MAY be one or more importers.
id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension (Importer)	Include a DUNS Number (without hyphens) for the importer.
There are two or more telecom elements	Include the name (company name) for the Importer agent.
The effective time year matches the current year.	Ensure that the year in the effective time field is the same as the current year.
If the document type is “Establishment registration”, then there is registrant information.	If the document type is “Establishment Registration,” then include registrant information.
Establishment registration has no labeler information	Do not submit information about the labeler in the Establishment Registration SPL document. Do not include the labeler code in the Establishment Registration SPL document.

Establishment Registration SPL

Determine the source of and locate the solution for the errors in one's Establishment Registration SPL document in the list below.

Error/Comment	Solution
If the document type is "Establishment registration", then there is registrant information.	If the document type is "Establishment Registration," then include registrant information.
Establishment registration has no labeler information	Do not submit information about the labeler in the Establishment Registration SPL document. Do not include the labeler code in the Establishment Registration SPL document.
Establishment has one or two id elements, one id, the DUNS number, and name are as in Section 2.1.5.	There should be a DUNS Number and an FEI number if it has been assigned. The name of the site should be included.
DUNS number is not associated with another establishment in the same SPL file.	Each establishment should have its own DUNS Number
For a "No change notification" (53410-7) or "Out of business notification" (53411-5) an Establishment Registration with the same setId has been previously submitted.	Do not submit a "No Change Notification" or "Out of Business Notification" Establishment Registration SPL document with a set ID unless you have already used this setID in a previously submitted technically valid Establishment Registration SPL document with the document type "Establishment Registration"
If the document type is "No change notification" or "Out of business notification", then there is no registrant information.	Do not include registrant information in a "No Change Notification" or "Out of Business Notification" documents. If you are using the SPL Xforms, do not just delete all of the registrant and establishment information from a previously submitted Establishment Registration SPL document. You should use the "SPLForm_Notification.xhtml" Xforms to create "No Change Notification" or "Out of Business Notification" documents.
If the document type is "No change notification" or "Out of business notification", then there is no establishment information.	Do not include establishment information in a "No Change Notification" or "Out of Business Notification" documents. If you are using the SPL Xforms, do not just delete all of the registrant and establishment information from a previously submitted Establishment Registration SPL document. You should use the "SPLForm_Notification.xhtml" Xforms to create "No Change Notification" or "Out of Business Notification" documents.

Establishment Registration SPL

Determine the source of and locate the solution for the errors in one's Establishment Registration SPL document in the list below.

Error/Comment	Solution
If a document with the same set id has been previously submitted, then it is an Establishment Registration (51725-0), No change notification (53410-7), or Out of Business Notification (53411-5).	If you have already used this set ID, you may not change the document type for an Establishment Registration SPL file (unless you are changing it to "Establishment De-Registration," "Out of Business Notification," or "No Change Notification.")

Contact and Address

This section includes the error messages and solutions for contact and address information in Establishment Registration SPL files.

Error/Comment	Solution
There is one contact party	Include the information for one contact entity
There is one contact person name	Include the name of one person as the contact person
The contactParty has an addr	The address should be included for the contact person
An address has street address line, city, and country	Include the street address line, city and country for each address
*If the country is "USA", then the contact party has a state (2 letters) and postal code	If the address is in the United States, include a state w/the two-letter abbreviation in capital letters and postal code in the address
*If there is no code attribute, then the country name may be the code, otherwise country is a full country name matching the code.	Enter the three-letter country code.
If the country is "USA", then the postal code is 5 digits with optionally a dash followed by 4 numbers	If the address is in the United States, include a postal code with five digits. After this zip code, you may include a dash followed by four numbers.
*If the country is not in the <i>postal code validation</i> list, then there is a postal code	Include a postal code unless the country in which your drug establishment is located does not have a postal code system.

Contact and Address

Contact and Address	
This section includes the error messages and solutions for contact and address information in Establishment Registration SPL files.	
Error/Comment	Solution
Country must be composed of letters only	Enter a three-letter country code (ISO 3166-1) Delete spaces included before or after country code. Link to 3-letter country code list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162567.htm
There are two or more <telecom> elements	Include a telephone number and an e-mail address
One telecom value begins with “tel:” and is a telephone number	Include “tel:” prior to the entering the telephone number
telephone numbers begin with “+”	Enter a “+” prior to entering the telephone number
telephone numbers must be global telephone numbers;	Enter a telephone number using the proper telephone format
telephone numbers contain no letters or spaces;	Enter the correct format for a telephone number Ensure that there are no spaces created with the keyboard space bar which are located before or after the telephone number.
There is one contact party	Include the information for one contact entity
There is one contact person name	Include the name of one person as the contact person
The contactParty has an addr	The address should be included for the contact person
Include hyphens to separate the country code, area codes and subscriber number	Use hyphens to separate the country code, area codes and subscriber number
have any extensions separated by “;ext=” (see Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966).	If there is an extension, separate the telephone number and the extension using “;ext=”
One telecom value begins with “mailto:” and encodes an email address.	Enter an e-mail address. Include “mailto:” prior entering the telephone number
'mailto:' is not a valid value for 'anyURI'.	Enter an e-mail address
an email address is of the simple form <username>@<dns-name>	- Enter a valid e-mail address - Remove spaces located before or after e-mail address that were created with keyboard space bar.

Contact and Address

This section includes the error messages and solutions for contact and address information in Establishment Registration SPL files.

Error/Comment	Solution
One telecom value begins with “mailto:” and encodes an email address.	Enter an e-mail address. Include “mailto:” prior entering the telephone number