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

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  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.  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 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 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 code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits	Error Message/Comment	Solution
submitted in documents of type "establishment registration" in the same or previous calendar year  - 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.  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 same application number.  If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  - Ensure that the type(s) of operation for each establishment is correct Ensure that the type(s) of operation for each establishment is correct Ensure that the type (s) of operation for each establishment is correct Ensure that the type (s) of operation for each establishment is correct Ensure that the type (s) of operation for each establishment is correct Ensure that the type (s) of operation of a cach establishment is correct Ensure that the type (s) of operation for each establishment is correct Ensure that the type (s) of operation of the same in this subsequent submission is the same in this subsequent submission If you are correcting an error or if you believe that the information year.  - Ensure that the type (s) of operation is the same in this subsequent submission If you are correcting an error or if you believe that the information year.  - Ensure that the type (s) of seach stablishment is calendar year Ensure that the product information is the same in this subsequent submission If you are correcting an error or if you	Act definition code matches code for an	- Ensure that the DUNS Number for the
"establishment registration" in the same or 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 us trength, product characteristics of size, shape, color and imprint code are the same as in the most recent submission for this NDC product/item code.  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 does not match any other id across all sections, documents, or any id other than the id of the same section previously submitted  If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits    Gach establishment is correct Ensure that the drug establishment has been registered this calendar year or at least the previous calendar year or at least the previous calendar year Ensure that the drug establishment has been registered this calendar year or at least the previous calendar year Ensure that the drug establishment is correct 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 vou entered is correct, send an e-mail to spl@da.hhs.gov with the core ID of the submission to request a manual override. If you request is NOT granted.  If the product is not previous submission of a product with the same application number.  If the co	establishment with same id previously	drug establishment is correct.
- Ensure that the drug establishment has been registered this calendar year or at least the previous calendar year or at least the previous 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.  If the code is C73584 (ANDA), C73585 (BLA), or C73594 (NDA) and the as in any previous submission of a product with the same application number.  If the code is C73584 (ANDA) and the as in any previous submission of a product with the same application number.  If the code is C73584 (ANDA), then the id of the same sections, documents, or any id other than the id of the same section previously submitted  If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  If the product information is the same in this subsequent submission.  If you are correcting an error or if you believe that the 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 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.  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 applicati	submitted in documents of type	- Ensure that the type(s) of operation for
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.  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 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 code is C73584 (ANDA), then the id of the same section previously submitted  If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  been registered this calendar year.  - 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 you 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 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.  If you change the content of a section, the section root ID has to be changed.  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 b	"establishment registration" in the same or	each establishment is correct.
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.  NDC product/item code.  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 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 code is C73584 (ANDA), c73585 (BLA), or C73594 (NDA) and the application number was already submitted, then the active ingredient of a product with the same application number.  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 code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  If the product information is the same in this subsequent submission.  - If you are correcting an error or if you believe that the information is the same in this subsequent submission.  - If you are correcting an error or if you believe that the 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@da.hhs.gov with the core ID of the submission to request is MOT granted.  If the product is associated with the marketing categories "ANDA," "BLA," or "NDA," and the application number been included in a previous SPL submission, the active ingredients' UNIIs have to be the sa	previous calendar year	- Ensure that the drug establishment has
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.  NDC product/item code.  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 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 code is C73584 (ANDA), c73585 (BLA), or C73594 (NDA) and the application number was already submitted, then the active ingredient of a product with the same application number.  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 code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  If the product information is the same in this subsequent submission.  - If you are correcting an error or if you believe that the information is the same in this subsequent submission.  - If you are correcting an error or if you believe that the 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@da.hhs.gov with the core ID of the submission to request is MOT granted.  If the product is associated with the marketing categories "ANDA," "BLA," or "NDA," and the application number been included in a previous SPL submission, the active ingredients' UNIIs have to be the sa		been registered this calendar year or at least
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.  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 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 code is C73584 (ANDA) 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.  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 sgranted, 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 product is associated with the marketing categories "ANDA," "BLA," or "NDA," and the application number has been included in a previous SPL submission of an SPL for a product with the same application number.  If you change the content of a section, the section root ID has to be changed.  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		the previous calendar year.
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.  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 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 code is C73584 (ANDA) 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.  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 sgranted, 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 product is associated with the marketing categories "ANDA," "BLA," or "NDA," and the application number has been included in a previous SPL submission of an SPL for a product with the same application number.  If you change the content of a section, the section root ID has to be changed.  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	If the NDC product/item code was	•
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.  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 does not match any other id across all sections, documents, or any id other than the id of the same section previously submitted  If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  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 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.  If you change the content of a section, the section root ID has to be changed.  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	previously submitted, then the product and	
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.  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 does not match any other id across all sections, documents, or any id other than the id of the same section previously submitted  If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  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 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.  If you change the content of a section, the section root ID has to be changed.  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	generic name, source, active ingredient	- If you are correcting an error or if you
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.  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 same application number.  If the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  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 granted, the file will be manually loaded. You will ONLY be notified via e-mail regarding your manual override. If you request is granted, the file will be manually loaded. You will ONLY be notified via e-mail regarding your manual override. If you request is granted, the file will be manually loaded. You will ONLY be notified via e-mail regarding your manual override. If you will only is granted, the file will be manually loaded. You will ONLY be notified via e-mail regarding your manual override. If you will only is granted, the file will be manually loaded. You will ONLY be notified via e-mail regarding your manual override. If you change the same as those in any previous submission of a product with the same application number.  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		•
shape, color and imprint code are the same as in the most recent submission for this NDC product/item code.  NDC product/item code.  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 code is C73584 (ANDA) 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 code is C73584 (ANDA) 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.  If you change the content of a section, the section root ID has to be changed.  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, is regulated by CBER as an ANDA."	_	correct, send an e-mail to spl@fda.hhs.gov
as in the most recent submission for this NDC product/item code.  NDC product/item code.  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 code is C73584 (ANDA) 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 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		with the <b>core ID</b> of the submission to
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.  If you change the content of a section, the section root ID has to be changed.  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		request a manual override. If your request
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.  If you change the content of a section, the section root ID has to be changed.  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	NDC product/item code.	is granted, the file will be manually loaded.
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.  If you change the content of a section, the section root ID has to be changed.  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		You will <b>ONLY</b> be notified via e-mail
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.  If you change the content of a section, the section root ID has to be changed.  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		regarding your manual override request if
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.  If you change the content of a section, the section root ID has to be changed.  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		
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.  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 the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  "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.  If you change the content of a section, the section root ID has to be changed.  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	If the code is C73584 (ANDA), C73585	
then the active ingredient UNIIs are the same as in any previous submission of 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 the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  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.  If you change the content of a section, the section root ID has to be changed.  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	(BLA), or C73594 (NDA) and the	marketing categories "ANDA," "BLA," or
then the active ingredient UNIIs are the same as in any previous submission of a product with the same application number.  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 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	application number was already submitted,	"NDA," and the application number has
with the same application number.  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 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 is regulated by CBER as an an an antipolar to the same as those in any previous submission of an SPL for a product with the same application number.  If you change the content of a section, the section root ID has to be changed.	_	
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 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 is regulated by CBER as an		submission, the active ingredients' UNIIs
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 the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  product with the same application number.  If you change the content of a section, the section root ID has to be changed.  If the product is regulated by CDER as an ANDA, the six-digit application number should be preceded by "ANDA."  If the product with the same application number section, the section root ID has to be changed.	with the same application number.	have to be the same as those in any
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 the code is C73584 (ANDA), then the id extension has the prefix "ANDA" or "BA" followed by 6 digits  If you change the content of a section, the section root ID has to be changed.  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 is regulated by CBER as an		previous submission of an SPL for a
sections, documents, or any id other than the id of the same section previously submitted  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		product with the same application number.
sections, documents, or any id other than the id of the same section previously submitted  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	id does not match any other id across all	If you change the content of a section, the
the id of the same section previously submitted  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		
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		
extension has the prefix "ANDA" or "BA" followed by 6 digits  ANDA, the six-digit application number should be preceded by "ANDA."  If the product is regulated by CBER as an	submitted	
extension has the prefix "ANDA" or "BA" followed by 6 digits  ANDA, the six-digit application number should be preceded by "ANDA."  If the product is regulated by CBER as an	If the code is C73584 (ANDA), then the id	If the product is regulated by CDER as an
followed by 6 digits should be preceded by "ANDA."  If the product is regulated by CBER as an	extension has the prefix "ANDA" or "BA"	-
If the product is regulated by CBER as an	followed by 6 digits	
ANDA, the six-digit application number		ANDA, the six-digit application number
should be preceded by "BA"		
If the code is C73594 (NDA) or C73605	If the code is C73594 (NDA) or C73605	· · · · · · · · · · · · · · · · · · ·
NDA authorized generic), then the id  NDA or NDA authorized generic, the six-		
extension has the prefix "NDA" or "BN" digit application number should be		_
followed by 6 digits preceded by "NDA"	followed by 6 digits	

	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.