Locating the Gateway Core ID & Downloading SPL Error Messages

Basic instructions for locating the Gateway Core ID and downloading SPL error messages. Version 1.0

Locating the Gateway Core ID

Log onto FDA Gateway

	Lo Lo						
M	My FDA submissions						
						Dther documents	
	Submission name	Size	Center	Туре	Status	Date	
	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCPP	SPL	Backup found Receipt Acknowledgement New	Oct 31, 2009 06:13:04 PM	

- Log onto the FDA Gateway
- Select the "My FDA submissions" or "Other documents" hyperlinks

Selecting the File w/Core ID

Center	Туре	Status	Date
OCPP	SPL	Backup found Receipt Acknowledgement New	Oct 31, 2009 06:13:04 PM

Click the "Acknowledgment" hyperlink

• The **first** "Acknowledgment" link should take you to window with core ID.

Finding the Core ID



- After selecting the "Acknowledgment" hyperlink, window should display.
- Core ID is located in top left of "Acknowledgment" window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.

Downloading Error Messages

Finding Error Messages

	WebTrader Help			_		Logout
M	/ FDA submissions					
						Other documents
	Submission name	Size	Center	Туре	Status	Date
	wellness_center.tar.gz	3 KB	OCPP	SPL	Backup found Receipt Acknowledgement Acknowledgement	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the "My FDA submissions" or "Other Documents" hyperlinks

Selecting Error Message

Size	Center	Туре	Status	Date
3 KB	OCPP	SPL	 <u>Backup found</u> <u>Receipt</u> <u>Acknowledgement</u> <u>New</u> <u>Acknowledgement</u> 	Oct 31, 2009 03:09:46 PM

Click on second (or third) "Acknowledgment" hyperlink

- Receipt of a second or third "Acknowledgment" hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) "Acknowledgment" hyperlink.

Opening Error Messages

Size	Center	Туре	Status	Date
3 KB	OCPP	SPL	Backup found Receipt Acknowledgement New	Oct 31, 2009 03:09:46 PM
				close
	ci12	570161	87076.9279@llntap01_te.xm	1
2.8 KB	O Fro To:	m: <u>FDATS</u> Lonnie	I e Smith (FDA)	
	Dat	e:	Nov 1, 2009 12:34	:11 PM EST
2.7 KB	O Sub <u>Viev</u>	mission n	nessageID: <18012736.12570 <u>nt</u>	16184535.JavaMail.smithlo@cdl0080685>
	0			
			Click "View document"	" hyperlink

• Click the "View Document" located in the bottom left corner of Acknowledgment prompt window.

Downloading Error Message

Axway - Document view - Microsoft Internet Explorer	
P	Help
Format options	
Choose how you want to view the document, or <u>download</u> the document to your computer. View as text View in browser - Choose this option to display the document in its unmodified form. Print Click "download" hyperlink	
<pre><?xml version="1.0" encoding="UTF-8"?><?xml-stylesheet href="http://www.accessdata. <document xmlns="urn:h17-org:</td><td>fda.gov/spl/spl_repo
:v3" xmlns:v="http://
:NT REGISTRATION" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"></document></pre>	

 Select the "download" hyperlink to download the error message to location on computer

Saving the Error Message Document

Axway - Document view - Microsoft Internet Explor		_ 🗆 🗙
P		Help
Format options Choose how you want to view the document, or	download the document to your computer.	
View as text View in browser - Choose this option to display the "Save" Select the "Save" Print button in "File Download" prompt	File Download Do you want to open or save this file? Name: ci1257016187076[1].9279@IIntap01_te.xml Type: Extensible Markup Language, 4.99 KB From: esgtest.fda.gov	
<pre><?xml version="1.0" encoding="UTF-8"?><? <document xmlns:xsi="http://www.w3.org/2 <id root="lbad7668-2756-421f-b389-7900 <code code="51725-0" codeSystem="2.16 <effectiveTime value="20091025"/> <setid 1"="" root="4728d6ce-6203-4cb5-8deb- <versionNumber value="></setid></pre>	Open Save Cancel While files from the Internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open or save this file. What's the insk?	spl/spl_repo s:v="http://

 Click the "Save" button in the "File Download" window prompt.

Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the "Save" button to save message in preferred location.

Completing Download



- You can open the message from the "Download complete" window prompt
- You can also close the window and directly open from location on your computer where message was stored.

Review the Error Message

🗿 Validation Report
Elle Edit View Favorites Iools Help
🕝 Back 👻 🔊 👻 😰 🏠 🔎 Search 🤺 Favorites 🤣 🎯 - 🌉 🕅 - 🛄 🔇 🏭 🦓
Address 🖹 C:\Documents and Settings\smithlo\Desktop\error_messages\ci1257016187076[1].9279@lintap01_te.xml 💟 🔁 Go
To help protect your security, Internet Explorer has restricted this file from showing active content that could access your computer. Click here for options
Validation Report
Document 1bad7668-2756-421f-b389-790b409f3786 (version 1) validated against validation procedures version 2 Revision 200910090048 on 2009-11-01 at 12:10 contained an error. For more information about SPL implementation please visit <u>Structured Product Labeling Resources</u> . Please contact <u>spl@fda.hhs.gov</u> if you have any questions or comments regarding this notification. If you would like test your SPL file prior to submitting to FDA, use the SPL validator accessible from this web page: <u>Validators</u> .
Overview of Errors

• Review the error message

Test Your SPL R4 Submissions

 Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:

http://www.fda.gov/ForIndustry/DataStand ards/ucm155514.htm

- NOTE
 - This validator tool is **NOT** connected to FDA database.
 - This tool assist you in detection of 90 95% of technical errors in SPL documents.

Submitting Files via FDA Gateway

Sena aocu	iment	
Sena doca		
Select who will	I receive the document	
Gateway: FDATS	ST	
Center: OC	Select the "OC" c	enter
Select the cont	tents of the submission	
Enter a path to a relative from the	a file or a directory. If a directory is entered, then the entire content provided directory path unless an alternate root directory is entered	s of the directory will be included in the submission. All the paths stored in the submission will be
Path:	C:/Documents and Settings/smithlo/Desktop/spl_submission	Ensure that you are submitting
Root directory:	C:/Documents and Settings/smithlo/Desktop/spl_submission	not appear in the path field)
Submission type:	* SPL	Select "SPI " as the submission type
	g certificate	Select OF L as the submission type
Select a signing		
Select a signing	SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12	

Stay Informed

- Join FDA Data Standards Council listserv
- <u>http://www.fda.gov/ForIndustry/DataStand</u> ards/default.htm

🕵 U.S. Department of Health & H	uman Services			🔊 www.hhs.gov
DA U.S. Food and Dru	ug Administration	A-Z Index	Search	199
Home Food Drugs Medical Devic	es Vaccines, Blood & Biologics An	imal & Veterinary Cosm	etics Radiation-Emittin	g Products Tobacco Products
or Industry		Email 1	his page 🖾 🛛 Print this p	age 🖨 Change Font Size 🖽 🗄
ome > For Industry > Data Standards				
Data Standards	FDA Resources for	S tandards		
Validators	💹 Sign up for email updat	es. 🗲		
Data Council	The FDA Data Standards Cou	incil coordinates the	evaluation, develop	ment, maintenance,
Structured Product Labeling	and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.			
Individual Case Safety Reports				
Regulated Product Submission				
	Structured Product Labeling			

SPL-related Technical Assistance/Questions

• SPL e-mail account (<u>spl@fda.hhs.gov</u>)