U.S. Food and Drug Administration



Step-by-Step Instructions for Electronic Self-Identification of Facilities, Sites, and Organizations

Generic Drug User Fee Amendment of 2012 (GDUFA)

Date: October 2012

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1 Introduction

This step-by-step document provides instructions on how to properly submit Structured Product Labeling (SPL) files to the FDA.

Figure 1: Self-Identification SPL Creation and Submission



2 Prerequisites for Self-Identification SPL Submission Files

Please reference the table below which includes a list of required pre-requisites which must be completed prior to starting the facility self-identification SPL Submission.

Requirement	Purpose	Duration estimate	Link
FDA FEI Number	Required to electronically Self- Identify and pay facility user fees	Via FDA: 10-15 business days	A facility that has not obtained an FEI may request one at: FDAGDUFAFEIRequest@ fda.hhs.gov Visit: http://go.usa.gov/vWm to verify an existing FEI number

Table 1: Prerequisites for Self-Identification SPL Submission

Requirement	Purpose	Duration estimate	Link
Facility DUNS Number	Required to electronically Self- Identify and pay facility user fees Note : A Facility DUNS number is used to match a facility user fee payment to the correct Facility Self- Identification submission	Standard Service (No Fee) : 30 – 45 days Expedited Service (Fee) : 3 – 5 days	A facility that has not obtained a DUNS number may request one at: <u>http://go.usa.gov/dHE</u> Visit: <u>http://go.usa.gov/vWm</u> to verify an existing DUNS number
Registrant DUNS Number	Required to electronically Self- Identify	Standard Service (No Fee) : 30 – 45 days Expedited Service (Fee) : 3 – 5 days	Same as above
Letter of Non- Repudiation to FDA	A letter of Non-Repudiation Agreement for digital signatures must be submitted to the FDA prior to registering as a transaction partner for the FDA Electronic Submission Gateway (ESG)	Standard Mail Delivery Service time	<u>http://go.usa.gov/dHV</u>
ESG Gateway Account	Required for secure electronic submissions transmission over the Internet	An account can be approved for production after FDA has received the Non-Repudiation letter referenced above (approximately 2 – 4 weeks)	<u>http://www.fda.gov/esg/1</u>
WebTrader Account	Preferred method for secure electronic submissions through the FDA ESG	An account can be approved for production after FDA has received the Non-Repudiation letter referenced above (approximately 2 – 4 weeks)	<u>http://go.usa.gov/dHm</u>
Digital/Electronic Signatures and Certificates	 The following signature methods are accepted by the FDA: Scanned signatures Digital signatures Flattened digital signatures A digital certificate binds together the owner's name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents for transmission 	User will need to contact a certificate vendor to obtain the certificate (dependent on the vendor)	<u>http://go.usa.gov/dta</u> <u>http://go.usa.gov/dH7</u>

3 Step 1: Creating Self-Identification SPL files

There are three options for creating a SPL file for performing electronic selfidentification of facilities, sites, and organizations.

- Option 1: FDA eSubmitter Tool
- Option 2: FDA Xforms
- Option 3: Internally Developed Tool
- Option 4: Commercially Available Tool

A globally unique identifier (GUID) is a special type of identifier needed to provide a unique reference number for the creation of SPL files. For more information about generating a GUID, go to:

http://www.guidgenerator.com/online-guid-generator.aspx

3.1 Option 1: FDA eSubmitter Tool

1. For more information on creating an SPL file using the FDA eSubmitter tool, go to:

http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

2. For more information on downloading and installing the FDA eSubmitter tool, go to:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm

Be sure to review the System Requirements section and see the FDA eSubmitter User Manual for complete downloading and installation instructions.

Note: Before installation, uninstall any other versions of the FDA eSubmitter Tool software. If you do not have a prior version of FDA eSubmitter Tool, proceed to installing the current version of FDA eSubmitter Tool.

To uninstall the previous versions of the FDA eSubmitter Tool, use Windows Explorer to navigate to the eSub folder of the installed drive (e.g., C:). Then, double-click on the uninstall.exe and follow the instructions provided. (If you do not see uninstall.exe, locate and double-click to open the JExpress file folder. Then, double-click on the uninstall.bat and follow the instructions provided.)

Figure 2: eSubmitter Welcome Screen Page

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ONS	stim. Welcome to eSubmitter! An FDA Electronic Submissions Software Initiative	Messa
e Submitter Q	Overview; This software application enables electronic submission of regulatory information to FDA in an effort to automate the submission process. It contains a number of data capturing tools and heipful allog boxes to reduce reductant responses, and to allow FDA to algore data in a nore used, il subtured format: These benefits enable chieffort within the FDA in survivo enable chieffort induce lengthy review times.	Tabs
Exit Application	Getting Startad: To familiare vorserf with the s/sounder application, see the "Getting Startad" section of the "resultender outs" duale", which provides information as well as tips for hanolytanging them to section in addition, the "sounder outse" also provides information on creating a new submission through to the submission packaging process. The "Submitter Guick Guide" can be surched from the corresponding menu (pilon on the left-hand see of the information or creating and the submitter Guick Guide" can be surched from the corresponding menu (pilon on the left-hand see of the information or creating and the submitter Guick Guide" can be surched from this corresponding menu (pilon on the left-hand see of the information or mere application to the submitter leave it submitted from this gap: Preset email any substitution or converting only in software application to the submitter leave its submitter duals the Preset email any submitter on any converting on the main of the submitter leave its submitter duals the Preset email any submitter on any converting on the application of the esubmitter leave its submitter duals the Preset email any submitter on any converting on the application of the esubmitter leave its submitter duals the Preset email any submitter on any converting on the information in the esubmitter duals the Preset email any submitter on any submitter on any submitter duals the	
	appropriate office. See Contacts/Addresses for further details.	Prima
	Application Updates; Updates to this software are automatic. These updates will occur, as available, if you are logged onto the internet at the time that the application is launched.	Scree
	Thank you again for using our electronic submission software. We look forward to hearing from you soon.	Area



Create New Submissio	n	
Step 1 Select Submission Type		4
List of Available Submission Types	147.	
Name	Version	Version Dat
BER/CDER: SPL Establishment Registration & Product Listing	1.0	08/29/2012 11:51:22
BER: BLA for Whole Blood and Blood Components, including Source Plasma	1.0	08/05/2012 08:43:7
>BER: ICSR Adverse Event Reporting for Pilot Testing	1.0	08/31/2012 10:00:57
BER: Investigational New Drug (IND) Applications in eCTD Structured Format	1.0	07/12/2012 02:03:35
DER/CBER: Generic Drug Facility Electronic Self-Identification	1.0	09/05/2012 11:57:42
DER: ICSR Drug Adverse Event Reporting	1.0	08/05/2012 08:15:40
DRH: 806 Corrections and Removal Reporting	1.0	05/08/2012 09:58:42
Description of Selected Submission Type		
Generic Drug Facility Electronic Self-Identification FDA is establishing databases, systems, and processes that help generic dru self-identification of facilities and sites involved in the development and man Electronic self-identification is requested by all such facilities and sites, whe required and if the facilities and sites are identified or intended to be identified drug submission. Those that are required to self-identify, whether or not the	ig companies perf iufacturing of gen ther or not user f id in an approved eir facilities or site	form electronic ieric drugs. Tees payments are or pending generic es are located within

3. For step-by-step instructions for creating and submitting a self-identification SPL file using the FDA eSubmitter tool, refer to the FDA eSubmitter Quick Guide – Generic Drug Facility Self-Identification document, go to:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm274477.htm

3.2 Option 2: FDA Xforms

1. For more information on creating an SPL file using Xforms, go to:

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/uc m189651.htm

- 2. Launch the Pragmatic Structures Product Labeling tool by clicking on the SPL Xforms link to launch the FDA Xforms tool.
 - a. For CDER, select "GDUFA Identification CDER" to create a selfidentification SPL file.
 - b. For CBER, select "GDUFA Identification CBER" to create a selfidentification SPL file.
- 3. Click "Load Template" to load the selected FDA Xforms template.

Note: The following fields are auto-populated when FDA Xforms are opened or template selected:

- Document ID
- Effective Time
- Version
- Set ID

You should NOT have to change this information unless you are updating the file to prepare a subsequent submission. If you need to alter the document tracking information, see the FDA Xforms Button Legend on previous page with instructions for using the buttons associated with these fields. (Note: to change the setID, delete the current setID with the computer keyboard's delete key.)

Figure 4: FDA Xform Page

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Copyright (c) 2010 Pragmatic Data L	LC. All rights reserved.		
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4. Continue to enter the needed information into the FDA Xform to self-identify your facility.

3.3 Options 3 & 4: Internally Developed and Commercially Available Tools

In-house developed and commercial tools can be used for self-identification, to utilize XML file formats which conform to Health Level Seven (HL-7) message exchange standards for SPL files.

Using commercial tools, self-identifiers can generate electronic SPL files and submit their SPL files through FDA's Electronic Submission Gateway (ESG). The technical details are available in the SPL Implementation Guide located on the FDA Data Standards Council Web site: http://www.fda.gov/oc/datacouncil/spl.html.

3.4 SPL File Content Restrictions

Currently, special characters are not supported by the SPL XML schema; therefore, the following special characters will not pass validation. Instead of the

special characters shown below, you must use the corresponding XML entity provided in the table.

 Table 2: Special Characters and Corresponding XML Entities

Special character that MAY NOT be used	Corresponding XML entity that MUST BE used instead
&	&
>	>
<	<
-	'
"	"

4 Step 2: Submitting an SPL File

Every SPL should be submitted using ESG. For additional information, please refer to the FDA ESG user guide web site at: <u>http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm</u>

The FDA Electronic Self-Identification supports two options for submitting an SPL file:

- Option 1: Web Interface
- Option 2: Gateway-to-Gateway

4.1 Requirements for an SPL File Submission

- All files must be submitted within a folder (each submission folder shall contain one .xml file and should not contain subfolders).
- All files must be in .xml format
- Each .xml file name must have an .xml extension and must conform to the naming convention described above.
- Individual files must not be compressed or archived.
- A folder submitted through the web interface (WebTrader) may not be archived (e.g., tar) nor compressed (e.g., gzip) because the submission process will automatically tar and gzip it.
- Folders submitted through the Gateway-to-Gateway protocol must be tar'ed and gzip'ed.

4.2 SPL File and Folder Naming

This section provides the special considerations that must be followed when naming facility self-identification SPL files and directories.

- Each SPL file must be named as follows: **rootID.xml**; where: **rootID** is a unique document identifier from the self-identification SPL.
- Each SPL file is placed in a folder. These are standard folders that are created on a local drive. There is no special requirement for the folder name—with the exception that the name cannot contain special characters (see the table below).

Table 3: Special characters not to be used in file and folder names

Character	Character Description
1	(forward slash)
١	(backslash)
:	(colon)
?	(question mark)
••	(quotation marks)
<	("less than" sign)
>	("greater than" sign)
	(vertical bar)
	Spaces: where a space is needed,
	please use_the_underscore_

4.3 Option 1: Web Interface

This section provides a production system URL and instruction for how to submit SPL files through the FDA ESG Gateway.

SPL files are placed in a folder and sent through the FDA ESG Gateway. The name of the "center" and the "submission type" are used to properly route the files. For GDUFA Electronic Self-Identification SPL files, the center is "CDER" and the submission type is "GDUFA".

The following screenshot illustrates a sample Web Trader Submission page.

Figure 5: Web Trader Submission Page

Do not show	v the alert message again		
Send de	ocument		
Select who	will receive the doci	iment	
Gateway: F	DATST		
Center:	CDER	•	
Select the	contents of the subm	ission	
Enter a path an alternate	to a file or a directory. root directory is entered	If a directory is entered, then th 1.	entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless
Path:+	C:/Users/bindu.m	andyam/Documents/Documents/	indu/GDUF Browse
Root directo	ory: C:/Users/bindu.m	andyam/Documents/Documents/	indu/GDUF Browse
Submission	type: GDUFA Facility R	egistration •	
Select a sig	gning certificate		
Current file:	: C:/Users/bindu.mandya	m/Documents/Documents/Bindu/	DUFA/GDUFA Certs/Himabindu Mandyam/Himabindu Mandyam Password.p12
New file:			Browse
	MyCertificate p12 or MyPriva	šeKey.přx	
Send			

Note: You must have an ESG account to execute the steps below.

- 1. Using the address provided by the FDA, access the FDA ESG Web Interface application. The Login page is displayed.
- 2. Enter the User ID and Password that was set up in the registration wizard. Click the Login button. The My FDA submissions page is displayed.
- 3. Click the WebTrader icon. The WebTrader drop-down menu is displayed.
- 4. Select the Send document menu item. The Send document page is displayed.
- 5. For CDER Submissions, select CDER from the Center drop-down box. The Center drop-down box is populated with CDER for the Center. For CBER Submissions, select OC from the Center drop-down box.
- 6. Click the Browse button associated with the Path textbox to select the submission. The submission file is displayed in the Path textbox.
- 7. For CDER Submissions, select the GDUFA Facility Registration submission type from the Submission type drop-down box. The GDUFA Facility Registration submission type is displayed in the Submission type drop-down box. For CBER Submissions, select the SPL submission type from the Submission type drop-down box.
- 8. Select a signing certificate by clicking the associated Browse button and select your appropriate certificate. The certificate is displayed in the New file textbox.
- 9. Click the Send button on the Send document page. The Enter password dialog box is displayed on top of the Send document page.
- 10. Enter the certificate password and click OK in the dialog box. The Upload Progress dialog box is displayed on the Send document page.

11. When the upload is complete (indicated by the display of Done), click the Close button in the Upload Progress dialog box. The submission is sent.

4.4 Option 2: Gateway-to-Gateway

Users are required to both tar (archive) and gzip (compress) multi-file submissions. Gzip is the native UNIX ZIP format and is used as a compression utility to reduce the size of the archive file.

For optimal transmittal of large submissions, first "tar" the files, and then compress the resulting .tar archive using the gzip utility. This process results in a .tar.gz extension.

5 User Support and Reference Information

5.1 Resources and Training Material

FDA GDUFA Web Page: http://go.usa.gov/vCt

- Guidance
- Federal Register Notices
- Public Meetings

FDA Facilities Self-Identification Electronic Submission Gateway (ESG): <u>http://go.usa.gov/duq</u>

FDA eSubmitter tool: http://go.usa.gov/dul

FDA eSubmitter tool Tutorial: <u>http://go.usa.gov/dzF</u>

FDA eSubmitter tool Quick Guide: <u>http://go.usa.gov/rsvm</u>

FDA Xforms: http://go.usa.gov/rswY

Commercial tools training and materials: <u>http://go.usa.gov/rsM3</u>

Note: For additional information on the SPL data requirements, please refer to the SPL Guidance for Industry: <u>http://go.usa.gov/rswe</u>

5.2 Technical Self-Identification Helpdesk and Questions

The FDA/CDER Facilities Self-Identification process: <u>CDEReFacility@fda.hhs.gov</u>

Step-by-Step Instructions for Electronic Self-Identification of Facilities, Sites, and Organizations for GDUFA

The FDA/CBER Facilities Self-Identification process: <u>SPL@fda.hhs.gov</u>

The FDA ESG submission process: <u>esgreg@gnsi.com</u> (technical issues) <u>esgprep@fda.hhs.gov</u> (preparation, registration, and policy issues)

FDA eSubmitter tool: esubmitter@fda.hhs.gov

FDA Xforms: SPL@fda.hhs.gov

Appendix A Self-identification SPL Sample

The following screen shots show a sample Self-identification SPL. The SPL contains registrant information and facility information (one foreign and one domestic), including the business operation qualifier.

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Step-by-Step Instructions for Electronic Self-Identification of Facilities, Sites, and Organizations for GDUFA

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Step-by-Step Instructions for Electronic Self-Identification of Facilities, Sites, and Organizations for GDUFA

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97					
98	<name>John Doe</name>				
99	<pre></pre>				
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Appendix B Data Element Definitions

This table contains a list of the element name, data type and definition for all of the date elements that are required for the self-identification SPL file.

Element Name	Data Type	Definition
documentType	String	SPL Document Type – unique identifier of SPL type (= Generic Drug Facility Identification Submission OR Identification of CBER-regulated Generic Drug Facility).
documentTypeCode	String	Document Type Code – matches SPL Document type (= 71743-9 OR 72090-4).
documentId	String	SPL Document ID – unique document identifier.
setId	String	SPL Set ID – unique identifier of the SPL Document that remains constant through all versions/revisions of the document.
versionNumber	Number	Version Number – a number that is incremented for each subsequent version number of the SPL document.
effectiveTime	Date	Effective Date – a revision date of the SPL document in YYYYMMDD format.
registrantDunsNumber	Number with leading zeros	Registrant DUNS Number – unique, 9-digit Dun & Bradstreet identifier of the Registrant.
registrantName	String	Registrant Name – name of the registrant registering the establishments.
registrantContactName	String	Registrant Contact Person Name.
registrantContactPhone	String	Registrant Contact Person Phone Number.
registrantContactEmail	String	Registrant Contact Person Email.
registrantContactStreet	String	Registrant Contact Mailing Address – street and number of the mailing address for the Registrant contact person.

Element Name	Data Type	Definition
registrantContactCity	String	Registrant Contact City – mailing address city for the Registrant contact person.
registrantContactState	String	Registrant Contact State – mailing address state for the Registrant contact person.
registrantContactPostalCode	String	Registrant Contact Postal Code – mailing address postal code for the Registrant contact person.
registrantContactCountry	String	Registrant Contact Country – three- character country code using the ISO 3166- 1 standard for the mailing address for the contact person.
establishmentDunsNumber	Number with leading zeros	Facility (Establishment) DUNS Number – unique, 9-digit Dun & Bradstreet identifier of the registered facility (establishment).
establishmentFeiNumber	Number with leading zeros	Facility (Establishment) FEI Number – unique 7- or 10-digit FDA Establishment Identifier (FEI).
establishmentName	String	Facility (Establishment) Name – name of the registered facility (establishment).
establishmentStreet	String	Facility (Establishment) Physical Mailing Address – street and number of the physical address of the registered facility (establishment).
establishmentCity	String	Facility (Establishment) Physical City – The city of the physical address of the registered facility (establishment).
establishmentState	String	Facility (Establishment) Physical State – mailing address state for the physical address of the registered facility (establishment).

Element Name	Data Type	Definition
establishmentPostalCode	String	Facility (Establishment) Physical Postal Code – mailing address postal code for the physical address of the registered facility (establishment).
establishmentCountry	String	Facility (Establishment) Physical Country – three-character country code using the ISO 3166-1 standard of the physical address of the registered facility (establishment).
establishmentContactName	String	Facility (Establishment) Contact Person Name.
establishmentContactPhone	String	Facility (Establishment) Contact Person Phone Number.
establishmentContactEmail	String	Facility (Establishment) Contact Person Email.
establishmentContactStreet	String	Facility (Establishment) Contact Mailing Address – street and number of the mailing address for the facility (establishment) contact person.
establishmentContactCity	String	Facility (Establishment) Contact City – mailing address city for the facility (establishment) contact person.
establishmentContactState	String	Facility (Establishment) Contact State – mailing address state for the facility (establishment) contact person.
establishmentContactZip	String	Facility (Establishment) Contact ZIP – mailing address postal code for the facility (establishment) contact person.
establishmentContactCountry	String	Facility (Establishment) Contact Country – three-character country code using the ISO 3166-1 standard for the mailing address for the facility (establishment) contact person.

Element Name	Data Type	Definition
establishmentOperation	String	 Facility (Establishment) Business Operation type of Operation performed at the Facility (Establishment). The following operations types can be used: API Manufacture (C82401) FDF Manufacture (C101510) Positron Emission Tomography Drug Production (C91403) Clinical Bioequivalence or Bioavailability Study (C101511) In Vitro Bioequivalence or Bioanalytical Testing (C101512) API/FDF Analytical Testing (C101509) Pack (C84731) Repack (C73606)
establishmentOperationCode	String	Business Operation Code – matches Business Operation (see Establishment Business Operations above).
operationIdentifier	String	Business Operation Identifier – identifies whether an establishment manufactures non-generic drugs (= Manufactures Non- Generics).