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)

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Table of Contents

1 Introduction 1
2 Prerequisites for Self-Identification SPL Submission Files 1
3 Step 1: Creating Self-Identification SPL files 3
3.1 Option 1: FDA eSubmitter Tool 3
3.2 Option 2: FDA Xforms 5
3.3 Options 3 & 4: Internally Developed and Commercially Available Tools 6
3.4 SPL File Content Restrictions 6
4 Step 2: Submitting an SPL File 7
4.1 Requirements for an SPL File Submission 7
4.2 SPL File and Folder Naming 8
4.3 Option 1: Web Interface 8
4.4 Option 2: Gateway-to-Gateway 10
5 User Support and Reference Information 10
5.1 Resources and Training Material 10
5.2 Technical Self-Identification Helpdesk and Questions 10
Appendix A Self-identification SPL Sample 12
Appendix B Data Element Definitions 15

List of Tables

Table 1: Prerequisites for Self-Identification SPL Submission 1
Table 2: Special Characters and Corresponding XML Entities 7
Table 3: Special characters not to be used in file and folder names 8

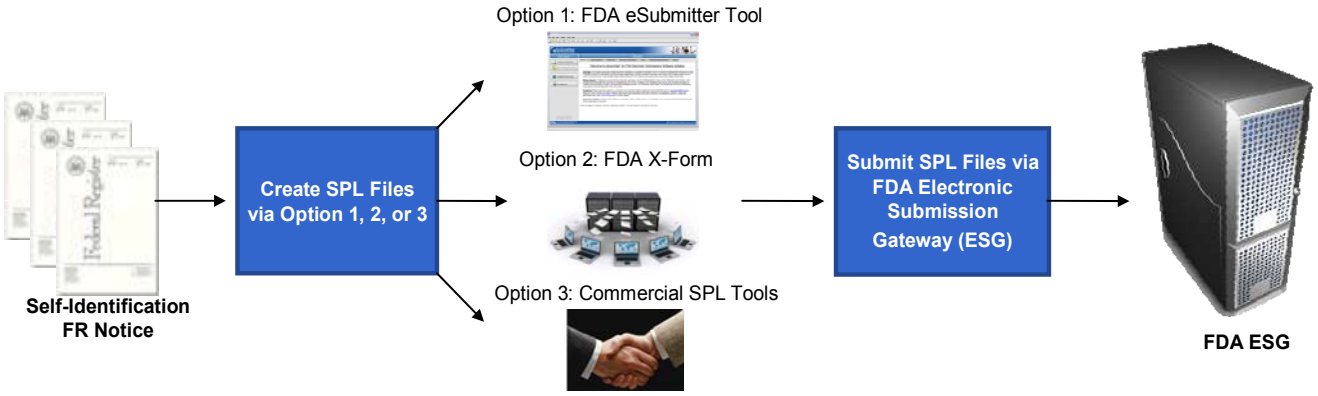
List of Figures

Figure 1: Self-Identification SPL Creation and Submission 1
Figure 2: eSubmitter Welcome Screen Page 4
Figure 3: eSubmitter Create a New Submission Page 4
Figure 4: FDA Xform Page 6
Figure 5: Web Trader Submission Page 9

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.

Table 1: Prerequisites for 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

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: http://go.usa.gov/dHE Visit: http://go.usa.gov/vWm 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	http://go.usa.gov/dHV
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)	http://www.fda.gov/esg/1
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)	http://go.usa.gov/dHm
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)	http://go.usa.gov/dta http://go.usa.gov/dH7

3 Step 1: Creating Self-Identification SPL files

There are three options for creating a SPL file for performing electronic self-identification 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

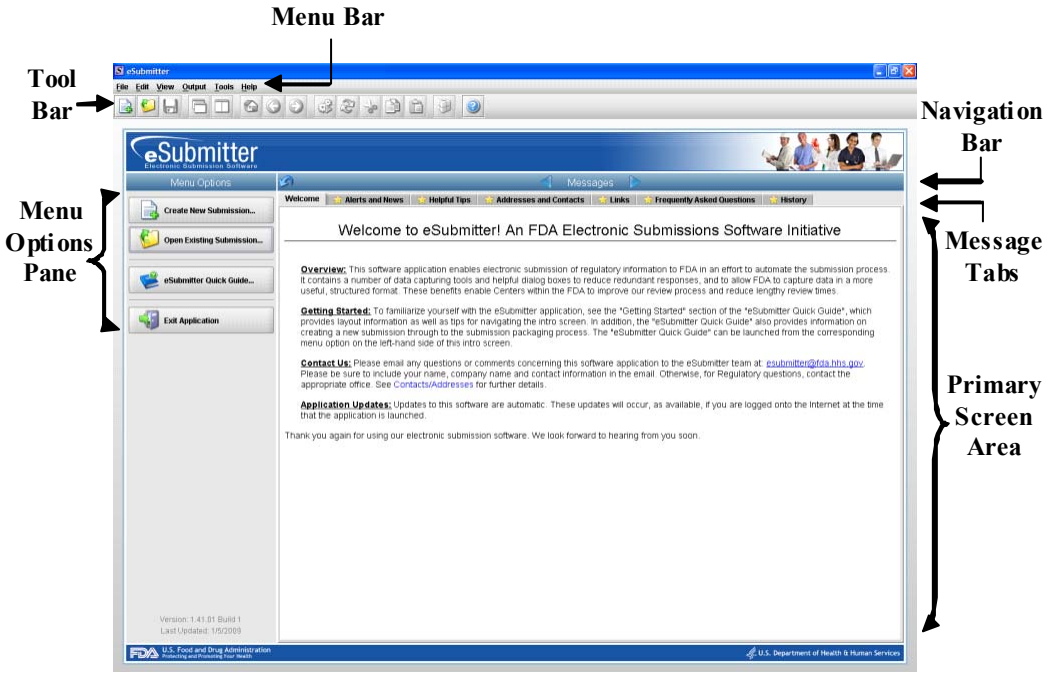
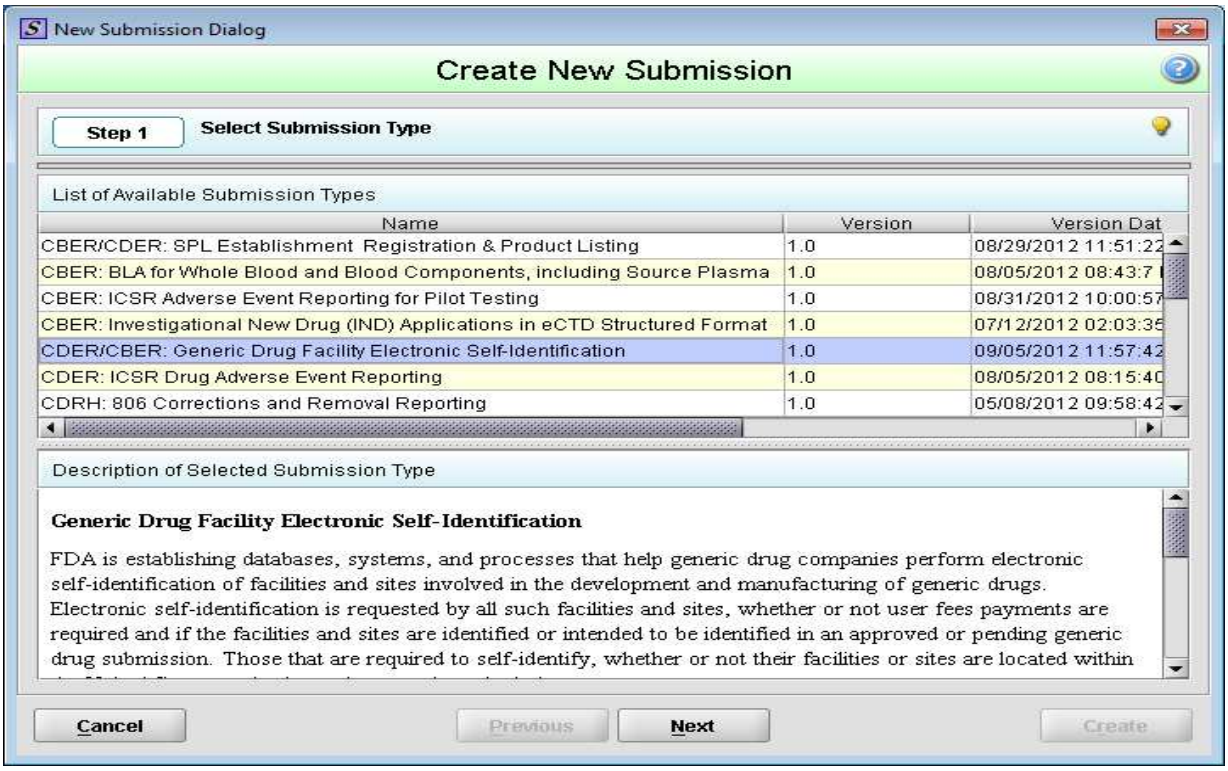


Figure 3: eSubmitter Create a New Submission Page



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/ucm189651.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 self-identification SPL file.

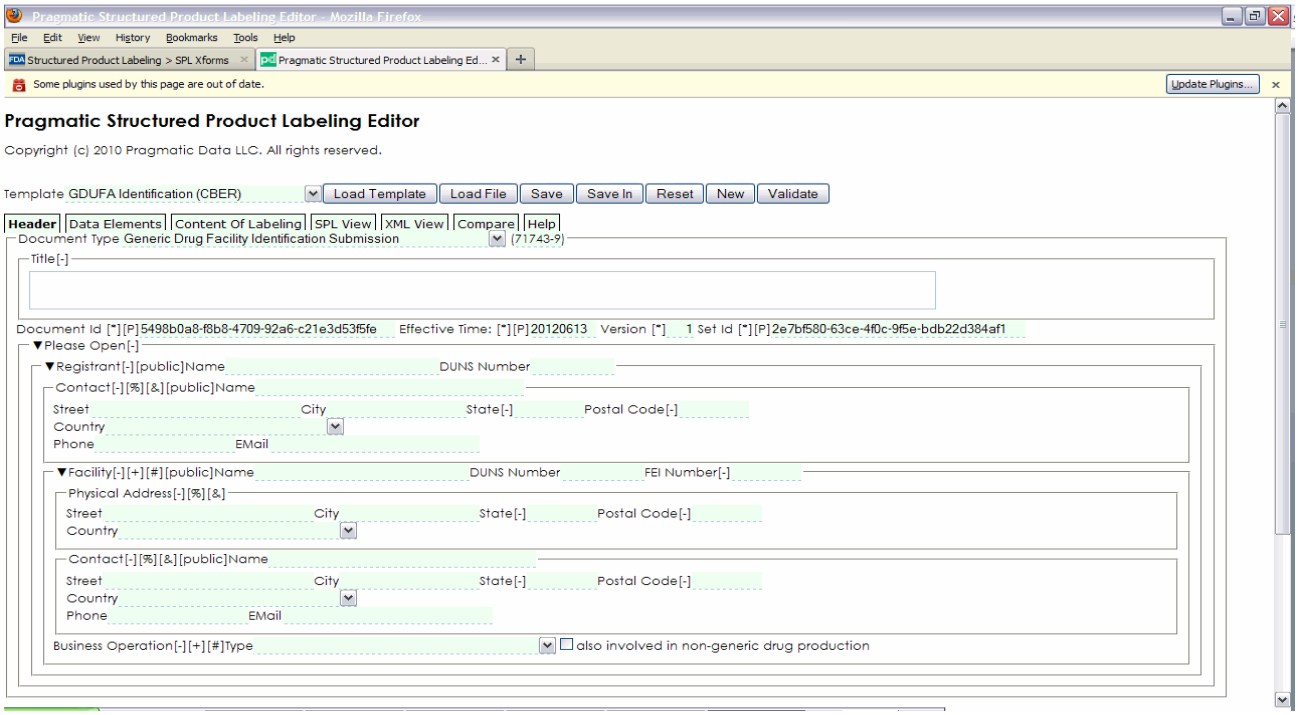
   b. For CBER, select “GDUFA Identification CBER” to create a self-identification SPL file.

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



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
&	&amp;
>	>
<	<
'	'
"	"

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:
http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm

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
/	(forward slash)
****	(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

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): http://go.usa.gov/duq

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

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

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

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

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

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

5.2 Technical Self-Identification Helpdesk and Questions

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

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

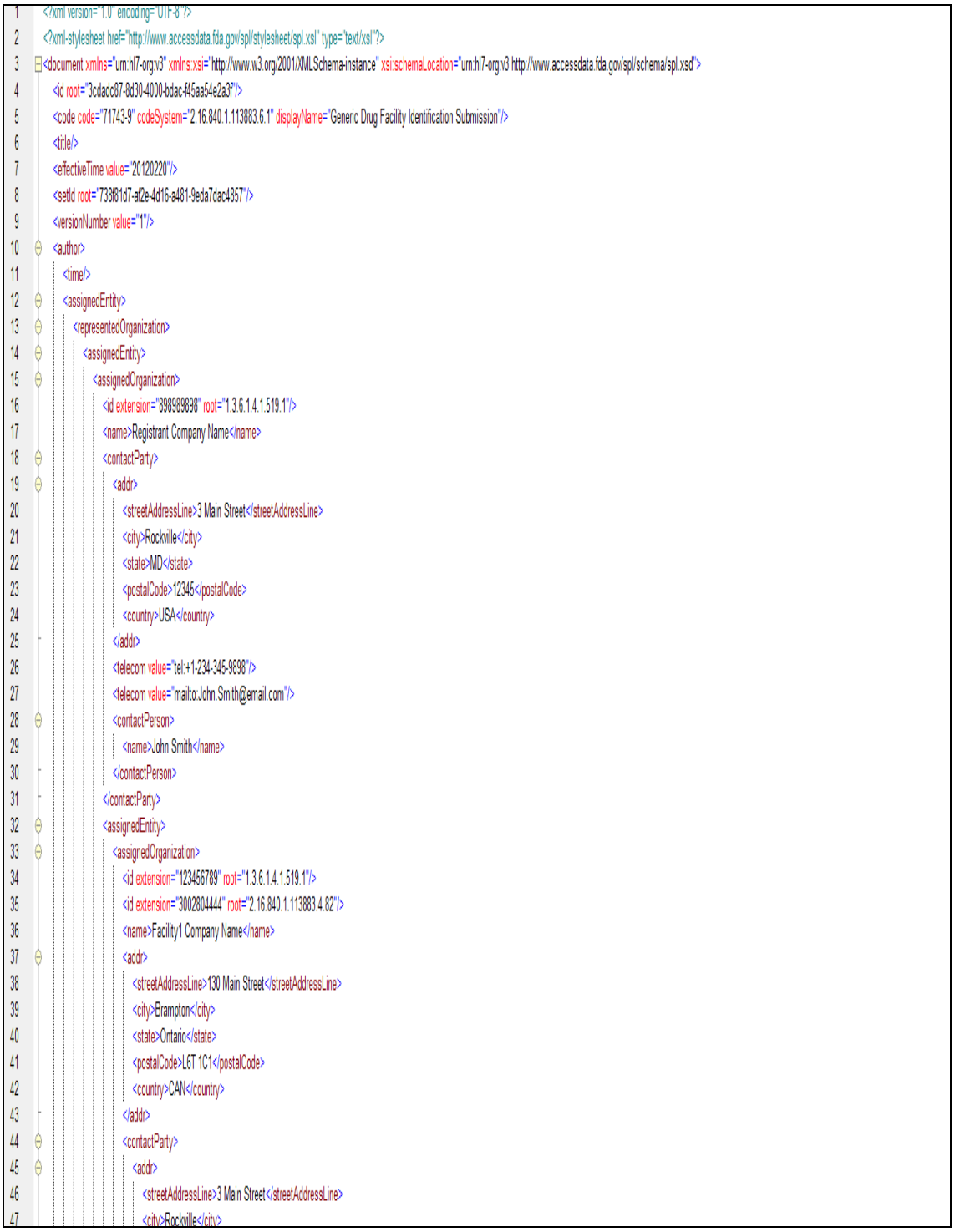
The FDA ESG submission process:
esgreg@gnsi.com (technical issues)
esgprep@fda.hhs.gov (preparation, registration, and policy issues)

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.



```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="http://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 http://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <id root="3cdadc87-8d30-4000-bdac-f45aa54e2a3f"/>
  <code code="71743-9" codeSystem="2.16.840.1.113883.6.1" displayName="Generic Drug Facility Identification Submission"/>
  <title/>
  <effectiveTime value="20120220"/>
  <setId root="738f81d7-af2e-4d16-a481-9eda7dac4857"/>
  <versionNumber value="1"/>
  <author>
    <time/>
    <assignedEntity>
      <representedOrganization>
        <assignedEntity>
          <assignedOrganization>
            <id extension="899989898" root="1.3.6.1.4.1.519.1"/>
            <name>Registrant Company Name</name>
            <contactParty>
              <addr>
                <streetAddressLine>3 Main Street</streetAddressLine>
                <city>Rockville</city>
                <state>MD</state>
                <postalCode>12345</postalCode>
                <country>USA</country>
              </addr>
              <telecom value="tel:+1-234-345-9898"/>
              <telecom value="mailto:John.Smith@email.com"/>
              <contactPerson>
                <name>John Smith</name>
              </contactPerson>
            </contactParty>
            <assignedEntity>
              <assignedOrganization>
                <id extension="123456789" root="1.3.6.1.4.1.519.1"/>
                <id extension="3002804444" root="2.16.840.1.113883.4.82"/>
                <name>Facility1 Company Name</name>
                <addr>
                  <streetAddressLine>130 Main Street</streetAddressLine>
                  <city>Brampton</city>
                  <state>Ontario</state>
                  <postalCode>L6T 1C1</postalCode>
                  <country>CAN</country>
                </addr>
                <contactParty>
                  <addr>
                    <streetAddressLine>3 Main Street</streetAddressLine>
                    <city>Rockville</city>
```

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                    <state>MD</state>
                    <postalCode>10532</postalCode>
                    <country>USA</country>
                  </addr>
                  <telecom value="tel:+1-567-345-9454"/>
                  <telecom value="mailto:Jane.Doe@email.com"/>
                  <contactPerson>
                    <name>Jane Doe</name>
                  </contactPerson>
                </contactParty>
              </assignedOrganization>
              <performance>
                <actDefinition>
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                  <subjectOf>
                    <approval>
                      <code code="C101886" displayName="Manufactures Non-Generics" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                    </approval>
                  </subjectOf>
                </actDefinition>
              </performance>
              <performance>
                <actDefinition>
                  <code code="C73606" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Repack"/>
                </actDefinition>
              </performance>
            </assignedEntity>
            <assignedEntity>
              <assignedOrganization>
                <id extension="123123123" root="1.3.6.1.4.1.519.1"/>
                <id extension="2432323" root="2.16.840.1.113883.4.82"/>
                <name>Facility2 Company Name</name>
                <addr>
                  <streetAddressLine>60 Main Road</streetAddressLine>
                  <city>Melville</city>
                  <state>NY</state>
                  <postalCode>11111</postalCode>
                  <country>USA</country>
                </addr>
                <contactParty>
                  <addr>
                    <streetAddressLine>60 Main Road</streetAddressLine>
                    <city>Melville</city>
                    <state>NY</state>
                    <postalCode>11111</postalCode>
                    <country>USA</country>
                  </addr>
```

```
                    </addr>
                    <telecom value="tel:+1-666-454-7878"/>
                    <telecom value="mailto:john.doe@company.com"/>
                    <contactPerson>
                      <name>John Doe</name>
                    </contactPerson>
                  </contactParty>
                </assignedOrganization>
                <performance>
                  <actDefinition>
                    <code code="C101510" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="FDF Manufacture"/>
                    <subjectOf>
                      <approval>
                        <code code="C101886" displayName="Manufactures Non-Generics" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                      </approval>
                    </subjectOf>
                  </actDefinition>
                </performance>
                <performance>
                  <actDefinition>
                    <code code="C82401" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="API Manufacture"/>
                  </actDefinition>
                </performance>
                <performance>
                  <actDefinition>
                    <code code="C84731" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Pack"/>
                  </actDefinition>
                </performance>
              </assignedEntity>
            </assignedOrganization>
          </assignedEntity>
        </representedOrganization>
      </assignedEntity>
    </author>
    <component>
      <nonXMLBody>
        <text/>
      </nonXMLBody>
    </component>
  </document>
```

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).