

## Instructions for using Electronic Drug Establishment Registration and Drug Listing XForms

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## 1 Preface

This document provides step by step instructions for creating Structured Product Labeling (SPL) file using drug establishment registration and drug listing XForms.

There are three XForms available for creating test SPL files; NDC Labeler Code request, Establishment registration and Drug Listing. The three XForms were developed by GlobalSubmit in collaboration with FDA. The XForms are available at no cost from the GlobalSubmit website at [www.globalsubmit.com/xportal](http://www.globalsubmit.com/xportal). From the GlobalSubmit website, the individual XForms may be downloaded for use on a local computer or the SPL files may created directly on the GlobalSubmit web site.

XForms are one way of creating an SPL file with drug registration and listing information. Because FDA has been accepting SPL files for product information since 2004, a number of solutions for creating SPL are available from individual vendors.

## 2 NDC Labeler Code Request Using XForms

The NDC Labeler Code request XForms is used to create an SPL file with information related to requesting a NDC Labeler Code. The following are instructions on filling out the relevant fields.

### 2.1 *Type of Document*

- Select “NDC Labeler Code request”.

### 2.2 *Document information*

The document information is used for tracking the SPL files and includes the id root, setId root, version number and effective time.

#### 2.2.1 **Id Root**

The id root uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID). A GUID is a string of numbers and lower case letters generated using a specifically defined mathematical algorithm to ensure a very low probability of identical GUID used in the same system. The XForms downloaded from the GlobalSubmit website includes the GlobalSubmit UUID Generator which can be used for generating a GUID. The GlobalSubmit GUID Generator is one of many software tools available for generating a GUID.

- To fill in this field, generate a GUID using the GlobalSubmit UUID Generator.
- Copy the generated identifier and paste it into the id root field.

#### 2.2.2 **Set ID Root**

The setId root uniquely identifies a group of versions of an SPL file. When an SPL file changes a **new** id root is assigned to the new SPL file but the setId root in the **original** SPL file is used. Like the id root, the setId root is a GUID.

- To fill in this field, generate a GUID using the GlobalSubmit UUID Generator.
- Copy the generated identifier and paste it into the setId root field.

#### 2.2.3 **Version number**

The version number provides an order for different versions of an SPL file. The version number is a whole number greater than zero. The version number is increased with each change.

- Enter a number in the version number field.

### **2.2.4 Effective Time**

The effective time provides a date reference to the SPL version. The date includes the year, month and day using the format yyymmdd.

- Enter the date for the SPL file.

## **2.3 Labeler**

The labeler is the registrant or private label distributor requesting the NDC Labeler Code. The information includes the labeler name and DUNS Number.<sup>1</sup>

### **2.3.1 Name**

- Enter the headquarters business name of the registrant or private label distributor.

### **2.3.2 DUNS Number**

Each business location (e.g., headquarters, branch, subsidiary, establishment, importer, US agent) has its own unique site specific DUNS Number.

- Enter the DUNS Number for the company headquarters.

### **2.3.3 NDC Labeler Code**

- Enter the 4 or 5 digit number assigned by FDA as the NDC Labeler Code.<sup>2</sup>

## **2.4 Labeler Contact**

The contact is the person FDA contacts regarding the NDC Labeler Code request. The contact information includes the name, address, contact telephone numbers and email address.

### **2.4.1 Name**

- Enter the name of the contact person

### **2.4.2 Mailing address**

- Enter the street and number of the mailing address for the contact person

### **2.4.3 City**

- Enter the city for the mailing address for the contact person

### **2.4.4 State**

- Enter the state for the mailing address for the contact person. If there is no state, as with certain addresses outside the United States, leave the field empty.

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<sup>1</sup> D-U-N-S® Number is from Dun and Bradstreet

<sup>2</sup> For minimally manipulated cells products, enter the 5character ISBT-128 site code

#### **2.4.5 Country**

- Enter the three character country code using the ISO 3166-1 standard for the mailing address for the contact person.

#### **2.4.6 Postal code**

- Enter the postal code for the mailing address for the contact person. If there is no postal code, as with certain addresses outside the United States, leave the field empty.

#### **2.4.7 Telephone number**

Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; include hyphens to separate the country code, area codes and subscriber number; extensions are separated by “;ext=”).

- Enter the contact telephone number for the contact person.

#### **2.4.8 Email Address**

- Enter the email address for the contact person.

### **2.5 Examples**

#### **2.5.1 Requesting a new NDC Labeler Code**

Fill out the *NDC Labeler Code request* as described in sections 2.1 through 2.4 leaving the NDC Labeler Code field empty.

Requests for NDC Labeler Codes are individually evaluated prior to entry into the NDC System. The initial request will be automatically stopped because there is no NDC Labeler Code provided and is diverted to a FDA reviewer. Once the evaluation is completed, the response to the request is directed to the designated contact person.

Once the NDC Labeler Code is assigned, open the original SPL file and add the newly assigned NDC Labeler Code and resubmit the corrected file.

#### **2.5.2 Initial electronic submission when NDC Labeler Code already assigned**

Fill out the *NDC Labeler Code request* as described in sections 2.1 through 2.4. Only one NDC Labeler Code is included in an SPL file. In other words, use a different setId root for each NDC Labeler Code request.

#### **2.5.3 Initial electronic submission for licensed minimally manipulated cell products**

Fill out the *NDC Labeler Code request* as described in sections 2.1 through 2.4 entering the 5 character ISBT-128 site code in place of the NDC Labeler Code. Only one ISBT-128 site code is included in an SPL file.

#### **2.5.4 Correct SPL file validation error**

If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person.<sup>3</sup> Open the SPL file and correct the errors.

#### **2.5.5 Correct a mistake in an SPL file just submitted**

Open the SPL file, correct the mistake, and fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

#### **2.5.6 Update the NDC Labeler Code information**

Open the previous SPL file and fill in the new information without changing the other existing information. Fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

#### **2.5.7 Requesting a second NDC Labeler Code**

Only one NDC Labeler Code is associated with each *NDC Labeler Code request*. If a second NDC Labeler Code is requested, fill out a separate SPL file with a **different setId root**. The labeler information and contact information is the same as the SPL file for the first NDC Labeler Code request.

### **3 Establishment Registration Using XForms**

The *Establishment registration* XForms is used to create an SPL file for establishment registration. A registrant includes all of their establishments in one *Establishment registration* SPL file. Each establishment is in only one *Establishment registration* SPL file. The following are instructions on filling out the relevant fields.

#### **3.1 Type of Document**

- Select “Establishment registration”.

#### **3.2 Document information**

The document information is used for tracking the SPL files and includes the id root, setId root, version number and effective time.

##### **3.2.1 Id Root**

The id root uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root.

- To fill in this field, generate a GUID using the GlobalSubmit UUID Generator.
- Copy the generated identifier and paste it into the id root field.

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<sup>3</sup> This report may be sent through the FDA Gateway, however, depending on the errors, the contact person may be contacted by phone or email.

### **3.2.2 Set ID Root**

The setId root uniquely identifies a group of versions of an SPL file. When an SPL file changes a **new** id root is assigned to the new SPL file but the setId root in the **original** SPL file is used. Like the id root, the setId root is a GUID.

- To fill in this field, generate a GUID using the GlobalSubmit UUID Generator.
- Copy the generated identifier and paste it into the setId root field.

### **3.2.3 Version number**

The version number provides an order for different versions of an SPL file. The version number is a whole number greater than zero. The version number is increased with each change.

- Enter a number in the version number field.

### **3.2.4 Effective Time**

The effective time provides a date reference to the SPL version. The date includes the year, month and day using the format `yyyymmdd`.

- Enter the date for the SPL file.

## ***3.3 Registrant***

The registrant is the owner or operator of the establishment registering the establishments. The information includes the registrant name and DUNS Number.

### **3.3.1 Name**

- Enter the headquarters business name of the registrant registering the establishments.

### **3.3.2 DUNS Number**

Each business location (e.g., headquarters, branch, subsidiary, establishment, importer, US agent) has its own unique site specific DUNS Number.

- Enter the DUNS Number for the company headquarters.

## ***3.4 Registrant Contact***

The contact is the person FDA contacts regarding the establishment registration information. The contact information includes the name, address, contact telephone numbers and email address.

### **3.4.1 Name**

- Enter the name of the contact person

### **3.4.2 Mailing address**

- Enter the street and number of the mailing address for the contact person

### **3.4.3 City**

- Enter the city for the mailing address for the contact person

### **3.4.4 State**

- Enter the state for the mailing address for the contact person. If there is no state, as with certain addresses outside the United States, leave the field empty.

### **3.4.5 Country**

- Enter the three character country code using the ISO 3166-1 standard for the mailing address for the contact person.

### **3.4.6 Postal code**

- Enter the postal code for the mailing address for the contact person. If there is no postal code, as with certain addresses outside the United States, leave the field empty.

### **3.4.7 Telephone number**

Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; include hyphens to separate the country code, area codes and subscriber number; extensions are separated by “;ext=”).

- Enter the contact telephone number for the contact person.

### **3.4.8 Email Address**

- Enter the email address for the contact person.

## **3.5 Establishment**

Establishment information includes the establishment name, DUNS Number, FDA Establishment Identifier (FEI), type of operation, contact information, US agent information and importation information.

### **3.5.1 Name**

- Enter the name of the establishment.

### **3.5.2 DUNS Number**

Each business location (e.g., headquarters, branch, subsidiary, establishment, importer, US agent) has its own unique site specific DUNS Number.

- Enter the DUNS Number for the establishment.

### **3.5.3 FEI**

FDA assigns an establishment identifier after the initial registration for tracking inspections.

- Enter the FEI number for the establishment. If not known, leave the field blank.

### **3.5.4 Physical address**

- Enter the street and number of the physical address of the establishment

### **3.5.5 City**

- Enter the city of the physical address of the establishment

### **3.5.6 State**

- Enter the state of the physical address of the establishment. If there is no state, as with certain addresses outside the United States, leave the field empty.

### **3.5.7 Country**

- Enter the three character country code using the ISO 3166-1 standard of the physical address of the establishment.

### **3.5.8 Postal code**

- Enter the postal code of the physical address of the establishment. If there is no postal code, as with certain addresses outside the United States, leave the field empty.

### **3.5.9 Type of operations**

- Enter the one or more drug manufacturing and processing operations performed at the establishment.

## **3.6 *Establishment Contact***

The contact is the person FDA contacts regarding the establishment. The contact information includes the name, address, contact telephone numbers and email address.

### **3.6.1 Name**

- Enter the name of the contact person

### **3.6.2 Mailing address**

- Enter the street and number of the mailing address for the contact person

### **3.6.3 City**

- Enter the city for the mailing address for the contact person

### **3.6.4 State**

- Enter the state for the mailing address for the contact person. If there is no state, as with certain addresses outside the United States, leave the field empty.



### **3.6.5 Country**

- Enter the three character country code using the ISO 3166-1 standard for the mailing address for the contact person.

### **3.6.6 Postal code**

- Enter the postal code for the mailing address for the contact person. If there is no postal code, as with certain addresses outside the United States, leave the field empty.

### **3.6.7 Telephone number**

Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; include hyphens to separate the country code, area codes and subscriber number; extensions are separated by “;ext=”).

- Enter the contact telephone number for the contact person.

### **3.6.8 Email Address**

- Enter the email address for the contact person.

## ***3.7 US Agent (Applicable only to establishments located outside the US)***

Information on the US agent includes the name, DUNS Number, telephone number and email address. Each establishment located outside the United States has one US agent.

### **3.7.1 Name**

- Enter the business name of the US agent.

### **3.7.2 DUNS Number**

Each business location (e.g., headquarters, branch, subsidiary, establishment, importer, US agent) has its own unique DUNS Number.

- Enter the DUNS Number for the US agent business.

### **3.7.3 Telephone number**

Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; include hyphens to separate the country code, area codes and subscriber number; extensions are separated by “;ext=”).

- Enter the contact telephone number for the US agent contact person.

### **3.7.4 Email Address**

- Enter the email address for the US agent contact person.

### ***3.8 Importer (Applicable only to establishments located outside the US)***

Information on business entities the establishment uses for importation (importer and person offering for import) includes the name, DUNS Number, telephone number and email address.

#### **3.8.1 Name**

- Enter the name of the business name.

#### **3.8.2 DUNS Number**

Each business location (e.g., headquarters, branch, subsidiary, establishment, importer, US agent) has its own unique DUNS Number.

- Enter the DUNS Number for the business.

#### **3.8.3 Telephone number**

Telephone numbers are global telephone numbers using the Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966 (no letters; begin with “+”; include hyphens to separate the country code, area codes and subscriber number; extensions are separated by “;ext=”).

- Enter the contact telephone number for the business contact person.

#### **3.8.4 Email Address**

- Enter the email address for the business contact person.

### ***3.9 Examples***

#### **3.9.1 Initial electronic submission for establishments already registered**

Registrants include information for all of their establishments in one *Establishment Registration* SPL file. Each establishment is in only one SPL file.

#### **3.9.2 Correct SPL file validation error**

If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.

#### **3.9.3 Correct a mistake in an SPL file just submitted**

Open the SPL file, correct the mistake, and fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

### **3.9.4 Update information for a registered establishment**

Open the previous SPL file and fill in the new information without changing the other existing information. Fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

### **3.9.5 Add a new establishment**

Open the previous SPL file and fill in the information on a new establishment without changing the information on the other establishments. Fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

### **3.9.6 Remove a previously registered establishment**

Open the previous SPL file, mark the establishment discontinued without changing the existing information on the other establishments. Fill in a new SPL file using a **new id root** and **new version number** with the **original setId**. At the next update, remove the specific establishment information.

### **3.9.7 No changes to registration information**

Each year when the information is updated, if there is no change, create an SPL file with the *document type* **No change notification** with a **new id root** and **new version number** with the **original setId** and the appropriate effective time. Registrant and establishment information is not included with an SPL file with the *document type* **No change notification**.

### **3.9.8 Registrant goes out of business**

If the registrant goes out of business, create an SPL file with the *document type* **Out of business notification** using a **new id root** and **new version number** with the **original setId** and the appropriate effective time. Registrant and establishment information is not included with an SPL file with the *document type* **Out of business notification**.

## **4 Drug Listing Using XForms**

The *Drug Listing* XForms is used to create an SPL file for drug listing. The drug listing information includes document information, labeler, registrant and establishment information, drug listing data elements and content of labeling. The entire drug listing information is included in a single SPL file. The following are instructions on filling out the fields for drug listing.

### **4.1 Type of Document**

- Click on the “Document Information” tab
- Select the type of document that corresponds to the product type being listed.

### **4.2 Document information**

The document information is used for tracking the SPL files and includes the id root, setId root, version number and effective time.

#### **4.2.1 Effective Time**

The effective time provides a date reference to the SPL version. The date includes the year, month and day using the format `yyyymmdd`.

- Enter the date for the SPL file.

#### **4.2.2 Id Root**

The id root uniquely identifies a specific SPL file. A new version of an SPL file has a new id root.

- To fill in this field, generate a GUID using the *GlobalSubmit UUID Generator*.
- Copy the generated identifier and paste it into the id root field.

#### **4.2.3 Set ID Root**

The setId root uniquely identifies a group of versions of an SPL file. When an SPL file changes a **new** id root is assigned to the new SPL file but setId root in the **original** SPL file is used. Like the id root, the setId root is a GUID.

- To fill in this field, generate a GUID using the *GlobalSubmit UUID Generator*.
- Copy the generated identifier and paste it into the setId root field.

#### **4.2.4 Version number**

The version number provides an order for different versions of an SPL file. The version number is a whole number greater than zero. The version number is increased with each change.

- Enter a number in the version number field.

### **4.3 Labeler**

The labeler uses their assigned NDC Labeler Code to create the NDC for the drug product. The information includes the name and DUNS Number.

#### **4.3.1 Name**

- Click on the “Drug Listing” tab
- Enter the business name of the labeler provided in the NDC Labeler Code request SPL file.

#### **4.3.2 DUNS Number**

- Enter the DUNS Number provided in the NDC Labeler Code request SPL file.

### **4.4 Registrant**

The registrant is included if they are listing a drug made for a private label distributor. The information includes the name and DUNS Number. Otherwise, this is blank.

#### **4.4.1 Name**

- Enter the business name of the registrant provided in the establishment registration SPL file.

#### **4.4.2 DUNS Number**

- Enter the DUNS Number of the registrant provided in the establishment registration SPL file.

#### **4.4.3 Mark as confidential**

- Check if the registrant information is confidential.

### ***4.5 Establishment***

The establishments are the entities involved in the manufacturing or processing the drug product. Enter one or more establishments. The information includes the name, DUNS Number and types of operations.

#### **4.5.1 Name**

- Enter the name of the establishment provided in the establishment registration SPL file.

#### **4.5.2 DUNS Number**

- Enter the DUNS Number of the establishment provided in the establishment registration SPL file.

#### **4.5.3 Type of operation**

- Select a type of operation performed at the establishment for this specific drug product.
- Click the “Add Type of Operation” button to add additional operations

#### **4.5.4 Mark as confidential**

- Check if the establishment information is confidential.

### ***4.6 Drug listing data elements one part***

The drug listing data elements include section identifiers and details on the drug product.

#### **4.6.1 Id Root**

The id root uniquely identifies the drug listing data elements section. A new id root is entered when the drug listing data element section changes.

- Click the “Add Product” button.
- To fill in this field, generate a GUID using the GlobalSubmit UUID Generator.
- Copy the generated identifier and paste it into the id root field.

#### **4.6.2 Effective Time**

The effective time provides a date reference to the section. The date includes the year, month and day using the format `yyyymmdd`.

- Enter the date for the section.

#### **4.6.3 Proprietary name**

The proprietary name is the brand or trade name without additional qualifiers such as “extra strength” or “XR”. Drug products that do not have a proprietary name include the non proprietary name without additional qualifiers as the proprietary name.

- Enter the proprietary name. If there is a suffix, leave a space after the name.

#### **4.6.4 Proprietary name suffix**

The proprietary name suffix is the additional qualifiers added to the proprietary name.

- Enter the proprietary name suffix. If no suffix, leave blank.

#### **4.6.5 Non proprietary name**

The non proprietary name is the established or proper name.

- Enter the non proprietary name.

#### **4.6.6 NDC Product Code**

The NDC Product Code is the NDC Labeler Code and the product segment of the NDC separated by a hyphen.<sup>4</sup>

- Enter the NDC Product Code

#### **4.6.7 Dosage form**

The *dosage form* of the drug product is the physical form as packaged. For example, a drug product used as an injection solution but is packaged as a powder that is reconstituted has a dosage form of “injection, powder, for solution”. For bulk drug, the “dosage form” is the physical form as packaged (e.g., powder)

- Select the appropriate dosage form from the drop down list.
- If the drug product has more than one drug product as a component, select “kit” as the dosage form and go to packaging.

#### **4.6.8 Source NDC Product Code**

The Source NDC Product Code is used when a marketed drug product is repacked or relabeled.

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<sup>4</sup> For licensed minimally manipulated cell products, enter the ISBT-128 5 character site code and 5 character product code separated by a hyphen

- Click the “Add Source NDC Product Code” button
- Enter the source NDC Product Code.

#### **4.6.9 DEA schedule**

- Click “Add DEA Schedule” button, if applicable
- Select the appropriate DEA schedule for the drug product.

#### **4.6.10 Route of administration**

- Click “Add Route of Administration” button
- Select the routes of administration approved for the drug product
- Repeat process for additional routes of administration

#### **4.6.11 Active ingredient name and UNII**

- Click “Add Active Ingredient” button if there are active ingredients
- Enter the preferred name and Unique Ingredient Identifier (UNII) for the active ingredient.
- Click “Add Active Ingredient” for additional active ingredients

#### **4.6.12 Active ingredient strength**

Strength is represented as a ratio. The numerator and denominator have a value and a unit. The value is the amount of ingredient for a dose (usually a whole number) based on either the active ingredient, active moiety or, in rare cases, another drug product. A powder that is reconstituted with a fixed amount is described as if it were reconstituted. For example, the strength of 10 mg of drug product packaged as powder in a vial to be reconstituted with 1 milliliter is 10 mg per 1 milliliter. A powder that is reconstituted with a variable amount is described as packaged. For example, the strength of 10 mg of drug product packaged as a powder in a vial to be reconstituted with 1 to 5 milliliters is 10 mg per 1.

- Enter the value and select the appropriate unit for the numerator and denominator for the strength.

#### **4.6.13 Reference drug**

Rarely, the strength of an active ingredient is based on a reference drug.

- Click “Add Reference drug” button if one is used as a basis of strength.
- Enter the reference drug

#### **4.6.14 Active moiety name and UNII**

There are one or more active moieties for each active ingredient.

- Enter the preferred name and UNII for the active moiety for the active ingredient.
- Click “Add Active Moiety” button for additional active moieties

#### **4.6.15 Basis of strength**

- Select if the active ingredient, active moiety or reference drug was used as the basis of the strength of the drug.

#### **4.6.16 Inactive ingredient name and UNII**

Inactive ingredients do not include products (mixtures of inactive ingredients) or ambiguous ingredients such as flavors, fragrances, undefined coatings or inks. Flavors and certain substances may be included as product characteristics (see below). In rare cases, the inactive ingredient may be flagged as confidential.

- Click “Add Inactive Ingredient” button if applicable
- Enter the preferred name and Unique Ingredient Identifier (UNII) for the inactive ingredients.
- Repeat process for additional inactive ingredients

#### **4.6.17 Inactive ingredient strength**

The strength of an inactive ingredient is included as needed. Strength is represented as a ratio. The numerator and denominator have a value and a unit. The value is the amount of ingredient for a dose.

- Enter the value and select the appropriate unit for the numerator and denominator for the strength.

#### **4.6.18 Mark as confidential**

- Check if the inactive ingredient information is confidential.

#### **4.6.19 Flavor**

Flavors are described as product distinctive characteristics rather than ingredients.

- Click “Add Flavor” button to include a flavor.
- Select the appropriate flavors.
- Enter additional description of the flavor into the original text field. If flavor and/or original text are not needed, leave the field blank.
- Repeat process for additional flavors

#### **4.6.20 Color**

- Click “Add Color” button to include a color
- Select the appropriate color.
- Enter additional description of the color into the original text field. If color and/or original text are not needed, leave the field blank.
- Repeat process for additional colors

#### **4.6.21 Score**

- Click “Add Imprint” button for describing solid oral dosage forms
- Select the appropriate score.



#### **4.6.22 Shape**

- Select the appropriate shape.
- Enter additional description of the shape into the original text field. If shape and/or original text are not needed, leave the field blank.

#### **4.6.23 Imprint code**

The imprint code is the alphanumeric text that appears on the solid dosage form, including text that is embossed, debossed, engraved or printed with ink. Internal and external cut-outs in the form of alphanumeric text and the letter 'R' with a circle around it (when referring to a registered trademark) and the letters 'TM' (when referring to a 'trade mark') are not included.

- Enter the imprint code by beginning on either side or part of the dosage form. Start at the top left and progress as one would normally read a book. Enter a semicolon to show separation between words or line divisions. If there is no imprint code, leave the field blank.

#### **4.6.24 Size**

Size is represented by the longest single dimension of the solid dosage form as a physical quantity in the dimension of length (e.g., 3 mm).

- Enter the value rounded to the nearest whole number in the size field
- Enter mm in the size unit field. If size is not relevant, leave the field blank.

#### **4.6.25 Marketing status and marketing date**

The marketing status describes the activity of the product and the marketing describes when the SPL file is added to the public repository of SPL files and when the SPL file is removed from the public repository. The expiration date of the last lot released to the marketplace provides an estimate of the date when the SPL file is removed.

- Select the appropriate product status of either “active” or “completed”.
- Select the appropriate start marketing date, if active or select the expiration date of the last lot marketed, if completed.

#### **4.6.26 Application or citation number and code system**

Application numbers include the character application abbreviation and the numbers without spaces or dashes (e.g., NDA123456). Monograph citations include the number of the regulatory part (e.g., part234).

- Enter the application number or the regulatory citation, if appropriate. If there is no application number or regulatory citation, leave the field blank.
- Select the appropriate code system

#### **4.6.27 Marketing category**

- Select the appropriate marketing category for the drug product.

#### **4.6.28 Product image**

- Click on “Add Product image” button to include an image of the dosage form received from FDA.
- Enter the file name for the image file.

#### **4.6.29 Packaging**

- Click on the “Add Package” button to add a new package configuration (e.g., samples carton of two, bottle of 30, carton of 100)
- Starting with the packaging configuration of the immediate unit of use. For a kit, the packaging starts with the quantity “1 Kit”.
- Enter the 10 character NDC Package Code. The NDC Package Code is the NDC Product Code and the package segment of the NDC separated by a hyphen.<sup>5</sup>
- Enter the quantity in the first field and the select the appropriate unit. The unit is the same as the denominator unit for the ingredient strength
- Select the appropriate package type
- Click on “Add Outer Package” button to add an outer retail package configuration and repeat the previous steps
- Click on “Add Package” button to add a new package configuration (e.g., samples carton of two, bottle of 30, carton of 100) and repeat the previous steps

#### **4.6.30 Product parts**

- Click on the “Add Product Part” button when the drug product has two or more drug components.
- Enter the proprietary name, proprietary suffix, non proprietary name, and dosage form as described in sections 4.6.3 through 4.6.7.
- Enter the total product quantity value as the total amount of the drug component in the kit with the appropriate unit.
- The rest of the information is completed as for products without parts.
- Click the “Add Product Part” button to add the second component and the repeat the steps.

### ***4.7 Content of labeling***

The content of the labeling provided with drug listing (e.g., professional labeling (package insert), consumer labeling, carton labels and container labels) is included in the same SPL file as the other drug listing information. Carton and container labels include the content of the Drug Facts or equivalent for animal drug products and the content of the Principal Display Panel including the image of the entire label as a single jpg file.

- Click on the “Content of Labeling” tab to begin

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<sup>5</sup> For licensed minimally manipulated cell products enter the ISBT-128 5 character site code and 5 character product code separated by a hyphen.

#### **4.7.1 Add title**

- Click on the “Add title” button
- Enter the title of the label. If there is no title, leave blank.

#### **4.7.2 Section**

- Click on the “Add Section” button.
- Select the first section.

#### **4.7.3 Add Hyperlink ID**

- Enter a unique ID in the ID field to identify the hypertext link ID.

#### **4.7.4 Title**

- Click on the “Add Title” to add a title for the section, if necessary

#### **4.7.5 Effective time**

- Click on “Add Effective time” button
- Enter the effective time using the format yyyyymmdd

#### **4.7.6 Highlights**

- If Highlights are needed, click on “Add Highlight” button
- Click on “Edit” button
- Enter Highlights text
- Save the entered text

#### **4.7.7 Section text**

- Click on “Edit” button
- Enter section text
- Save the entered text

#### **4.7.8 Media**

- Click on “Add media” button to add figure
- Enter ID for figure

#### **4.7.9 Subsection**

- Click on “Add Subsection” button
- Repeat steps above

#### **4.7.10 Next Section**

- Click on “Add Section” to add next section.
- Repeat for the other sections. The sections are included in order of how they appear in the labeling.

## **4.8 Examples**

### **4.8.1 Initial listing submission when release 3 SPL file previously submitted**

Update the previous SPL release 3 file to an SPL release 4 file with the additional drug listing information and submit a new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.

### **4.8.2 Initial listing submission with drugs previously listed**

The drug listing information is provided in a single SPL file. More than one drug products are included in a single SPL file when the products relate to the same content of labeling. Each drug product is included in only one SPL file unless it is being repacked or relabeled. Note that drug listing includes all jpg files associated with the content of labeling. The drug listing SPL file is separate from the SPL file for NDC Labeler Code request and the SPL file for establishment registration.

### **4.8.3 Initial listing submission when the private label distributor provides the SPL file**

If the private label distributor chooses to provide the SPL file with the drug listing information, the private label distributor includes all of the information that would have been supplied by the registrant including all establishments involved in the manufacturing and processing of the drug product. The registrant does **not** submit a drug listing SPL file for this drug product. If the private label distributor chooses not to provide the SPL file with the drug listing information, then the registrant provides the SPL file.

### **4.8.4 Initial listing submission when the registrant provides the SPL file for a drug made for a private label distributor**

If the private label distributor chooses not to provide the SPL file with the drug listing information, then the registrant provides the SPL file. The registrant includes the name of the private label distributor as the labeler, itself as the registrant, and all establishments involved in the manufacturing and processing of the drug.

### **4.8.5 Initial listing submission with more than one registrant involved**

When more than one registrant is involved in manufacturing and processing a single drug product (e.g., contract manufacturers), only one registrant provides the SPL file with the drug listing information for the drug product. The registrant who provides the SPL file includes, in addition to its own establishments, all establishments of the other registrants involved in the manufacturing and processing of the drug product.

#### **4.8.6 Initial listing submission for bulk ingredients**

The registrant provides the SPL file with the drug listing information for the bulk drug ingredients (e.g., active pharmaceutical ingredient).

#### **4.8.7 Initial listing submission for a registrant using a marketed bulk ingredient**

The registrant provides the SPL file with the drug listing information for its drug product. The registrant includes the NDC Product Code for the marketed bulk drug ingredient as the source NDC or the establishments used in manufacturing or processing the bulk ingredient.

#### **4.8.8 Initial listing submission for a registrant repacking or relabeling a marketed drug product**

The repacker or relabeler provides the SPL file with the drug listing information for its drug product including the NDC Product Code for the source marketed drug product.

#### **4.8.9 Initial listing submission for a kit including two or more drug products**

The registrant or private label distributor provides the SPL file with the drug listing information for its kit. The SPL file also includes drug listing information for each drug product in the kit (component) including NDC Product Codes and NDC Package Codes, if applicable.

#### **4.8.10 Correct SPL file validation error**

If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.

#### **4.8.11 Correct a mistake in an SPL file just submitted**

Open the SPL file, correct the mistake, and fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

#### **4.8.12 Update information for a listed drug product**

Open the previous SPL file and fill in the new information without changing the other existing information. Fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

#### **4.8.13 Add a new drug product**

Open the previous SPL file and fill in the information on a new drug product without changing the information on the other drug products. Fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

#### **4.8.14 Discontinue a previously listed drug product**

Open the previous SPL file and update the marketing activity with the expiration date for the last lot released for the specific drug product information without changing the existing information on the other drug products. Fill in a new SPL file using a **new id** and

**new** version number with the **original** setId and the appropriate effective time. Once the drug is discontinued, open the most recent SPL file and remove the specific drug product information without changing the existing information on the other drug products. Fill in a new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.

#### **4.8.15 Change in content of labeling not requiring prior approval<sup>6</sup>**

Open the previous SPL file and change the content of labeling without changing the other existing drug listing information. Fill in the new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.

#### **4.8.16 Add a package configuration**

Open the previous SPL file and add the new package configuration without changing the other existing drug listing information. Fill in the new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.

#### **4.8.17 Remove a package configuration**

Open the previous SPL file and remove the specific package configuration without changing the other drug listing information. Fill in the new SPL file using a **new** id and **new** version number with the **original** setId and the appropriate effective time.

## **5 Sending in SPL files**

The **root id** from the document identifiers is used for the name of the SPL file with the extension “xml”. The version number is increased for every subsequent submission that is successfully processed by the FDA system (i.e., does not fail validation). The Agency communicates with the designated contact person using email if there are problems.

SPL files including all image files are placed in a folder and sent through the FDA Gateway. Instructions for using the FDA Gateway are found on the FDA Web site at <http://www.fda.gov/esp>. The name of the “center” and the “type of submission” are used to properly route the files. For electronic drug registration and listing, the center is “OC” and the type of submission is “SPL”.

## **6 Technical assistance**

Send an email to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov) for technical assistance.

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<sup>6</sup> These include content of labeling changes provided with an annual report (e.g., 21 CFR 314.70(d)), content of labeling with changes being effected for safety reasons (e.g., 21 CFR 314.70(c)(6)(iii)) and approved content of labeling (e.g., final labeling).