FOOD & DRUG ADMINISTRATION

OFFICE OF INFORMATION MANAGEMENT (OIM)

DIVISION OF SYSTEMS (DOS)

Affordable Care Act (ACA) 6004

ACA Industry Submission Specifications User Guide

Table of Contents

1. Background

On March 23, 2010, the Affordable Care Act (ACA) was signed into law. Among other things, the ACA amends the Social Security Act (42 U.S.C. 1301 et seq.) by adding section 6004.

This new section explicitly states that manufacturers and authorized distributors must submit to FDA, on or before April 1st, 2012, and each year thereafter, certain drug sample information for the previous year.

2. Purpose and Scope

This document provides FDA Sponsors (a.k.a. "Industry" or "Partners") with the technical requirements for the proper submission of files to FDA's ACA6004 system through FDA's Electronic Submissions Gateway (ESG).

3. Drug Sample submission through ESG Gateway

This section provides a production system URL and instruction for how to submit "ACA 6004 Drug Samples" through gateway.

The Gateway URL is: https://esg.fda.gov

The following screenshot illustrates the selection of the "ACA 6004 Drug Sample" option from the "Submission type" dropbox on the FDA Gateway submission page.

Figure 1: Web Trader Submission page

4. File and Folder Naming Convention

This section provides the special considerations that must be followed when naming ACA6004 files and directories.

- Each file must be named as follows:

    `ShortNameFirm_SubmissionYear_mm-dd-yyyy_n.xml`

  where

    - `ShortNameFirm` is a brief form of your company's name
    - `SubmissionYear` is a YYYY-form representation of the data's year
    - `mm-dd-yyyy` is the submission date
    - `n` is a sequence number (1, 2, …) for multiple files being submitted on the same day

- A file name's length, including .xml extension, may not exceed 112 characters

- Each folder must be named as follows:

    `ShortNameFirm_ACA6004_SubmissionYear_n`

  where

    - `ShortNameFirm` is a brief form of your company's name.
    - `SubmissionYear` is a YYYY-form representation of the data's year.
    - `n` is a sequence number (1, 2, …) for multiple folders being submitted.

- File and folder names may not contain any of these special characters:
    - `/` (forward slash)
    - `\` (backslash)
    - `:` (colon)
    - `?` (question mark)
    - `"` (quotation marks)
    - `<` ("less than" sign)
    - `>` ("greater than" sign)
    - `|` (vertical bar)
    - Space (where a space is needed, use_an_underscore_instead or SeparateWordsWithCapitalLetters.

5. Restriction on the XML File's Contents

Currently, special characters are not supported by the ACA6004's XML schema. Therefore, the following special characters will not pass validation. Instead of each character, you must use the corresponding XML entity as shown below:

Special character which may not be used	Corresponding XML entity which must be used
&	&
>	>
<	<
'	'
"	"

6. Requirements for ACA6004 Submission Files

- All files must be submitted within a folder (each submission folder shall contain one or more XML files and should not contain subfolders)

- All files must be in XML format and **must be validated** against the FDA-provided XML schema before submission.

  The link to the ACA 6004 XML schema can be found at this URL:
  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm

- Each XML file's name must have an .xml extension and must conform to the naming convention described above.

- Each individual file must be smaller than or equal to 200MB

- Total folder size may exceed 200MB but must not exceed 2GB in size

- 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.

7. Submission to ESG

For further guidance, please refer to the ESG user guide at:

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

7.1 Web Interface Submission to ESG

During the folder upload process, the FDA ESG Web Interface utilizes the tar functionality for file system consolidation when submitting folders. The process occurs during the electronic "signing" of the submission. Before the folder is transmitted, it is tar'ed and gzip'ed, encrypted, signed, and mime-wrapped (or packaged) before transmitting to the FDA ESG.

The .tar.gz (compressed archive) folder should not contain any file or sub-directory that has a "." (dot) at the beginning of its name.

Because this process is done automatically during the signing of the file, no intervention is required from the user to ensure the folder is tar'ed and gzip'ed.

7.2 Gateway-to-Gateway Submission to ESG

Partners 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.

8. General Information

All necessary information will be communicated through the ACA web site

- ACA website Links:
  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm

- The FDA's Electronic Submissions Gateway (ESG) web site:
  http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

- The FDA's Electronic Submissions Gateway (ESG)user guide:
  http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm

Appendix 1 FDA ACA XML Schema

```xml
<xsd:schema xmlns:xsd="http://www.w3.org/2001/XMLSchema" xmlns:tns="aca"
targetNamespace="aca" elementFormDefault="unqualified"
attributeFormDefault="unqualified">
	<xsd:annotation>
		<xsd:documentation xml:lang="en">ACA 6004 Submission
Definition</xsd:documentation>
	</xsd:annotation>
	<xsd:element name="submission" type="tns:SubmissionType"/>
	<xsd:complexType name="SubmissionType">
		<xsd:sequence>
			<xsd:element name="submissionYear" type="xsd:gYear">
				<xsd:annotation>
					<xsd:documentation xml:lang="en">This is the calendar
year the sample being reported was distributed to the
Practitioner/recipient.</xsd:documentation>
				</xsd:annotation>
			</xsd:element>
			<xsd:element name="business" type="tns:Business"/>
			<xsd:element name="practitionerGroups"
type="tns:PractitionerGroups"/>
		</xsd:sequence>
	</xsd:complexType>
	<xsd:complexType name="PractitionerGroups">
		<xsd:sequence>
			<xsd:element name="practitionerGroup" maxOccurs="unbounded">
				<xsd:complexType>
					<xsd:sequence>
						<xsd:element name="practitioner"
type="tns:PractitionerType"/>
						<xsd:group ref="tns:sample"
maxOccurs="unbounded"/>
					</xsd:sequence>
				</xsd:complexType>
			</xsd:element>
		</xsd:sequence>
	</xsd:complexType>
	<xsd:group name="sample">
		<xsd:sequence>
			<xsd:element name="tradeNameDosage">
				<xsd:simpleType>
					<xsd:annotation>
						<xsd:documentation xml:lang="en">This refers to
the trade name and dosage of the drug sample distributed. For example, "Synthroid
0.1mg".</xsd:documentation>
					</xsd:annotation>
```

```xsd
                                <xsd:restriction base="xsd:string">
                                        <xsd:minLength value="1"/>
                                        <xsd:maxLength value="100"/>
                                        <xsd:whiteSpace value="collapse"/>
                                </xsd:restriction>
                        </xsd:simpleType>
                </xsd:element>
                <!--
        <xsd:element name="NDCNumber">
            <xsd:annotation>
                <xsd:documentation xml:lang="en">Reserved for future use. Unique Identifier for
drug products</xsd:documentation>
            </xsd:annotation>
            <xsd:simpleType>
                <xsd:restriction base="xsd:string">
                    <xsd:minLength value="1"/>
                    <xsd:maxLength value="50"/>
                    <xsd:whiteSpace value="collapse"/>
                </xsd:restriction>
            </xsd:simpleType>
        </xsd:element>
        -->
                        <xsd:element name="pkgSize">
                                <xsd:simpleType>
                                        <xsd:annotation>
                                                <xsd:documentation xml:lang="en">A description
of the size and type of packaging in sentence form. For example: 4 BOTTLES in 1
CARTON/100 TABLETS in 1 BOTTLE. Sample packages will often be smaller the than
example given.</xsd:documentation>
                                        </xsd:annotation>
                                        <xsd:restriction base="xsd:string">
                                                <xsd:minLength value="1"/>
                                                <xsd:maxLength value="100"/>
                                                <xsd:whiteSpace value="collapse"/>
                                        </xsd:restriction>
                                </xsd:simpleType>
                        </xsd:element>
                        <xsd:element name="pkgQtyReq">
                                <xsd:annotation>
                                        <xsd:documentation xml:lang="en">This data element
should be aggregated by the practitioner making the request. It should state the total quantity of
the drug (trade name and dosage) requested during the calendar year.</xsd:documentation>
                                </xsd:annotation>
                                <xsd:simpleType>
                                        <xsd:restriction base="xsd:string">
```

```
                            <xsd:minLength value="1"/>
                            <xsd:maxLength value="100"/>
                            <xsd:whiteSpace value="collapse"/>
                        </xsd:restriction>
                    </xsd:simpleType>
                </xsd:element>
                <xsd:element name="hasReqSignature"
type="tns:AffirmationSignatureType" default="N">
                    <xsd:annotation>
                        <xsd:documentation xml:lang="en">Affirmation
regarding signature on written request. A one character (Y = Yes, N = No) data element which
affirms that the manufacturer or distributor has the signature on file for the sample request. This
has been included to avoid placing a burden on firms who would otherwise need to send in an
image of the signature.</xsd:documentation>
                    </xsd:annotation>
                </xsd:element>
                <xsd:group ref="tns:receivedSample" maxOccurs="unbounded"/>
            </xsd:sequence>
        </xsd:group>
        <xsd:group name="receivedSample">
            <xsd:sequence>
                <xsd:element name="designee" type="tns:DesigneeType"
minOccurs="0"/>
                <xsd:element name="pkgQtyDist">
                    <xsd:annotation>
                        <xsd:documentation xml:lang="en">This data element
should be aggregated by the practitioner or the recipient (designee) who signed for the sample
distribution. It should state the total quantity of the drug (trade name and dosage) distributed
during the calendar year.</xsd:documentation>
                    </xsd:annotation>
                    <xsd:simpleType>
                        <xsd:restriction base="xsd:string">
                            <xsd:minLength value="1"/>
                            <xsd:maxLength value="100"/>
                            <xsd:whiteSpace value="collapse"/>
                        </xsd:restriction>
                    </xsd:simpleType>
                </xsd:element>
                <xsd:element name="hasReceiptSignature"
type="tns:AffirmationSignatureType" default="N">
                    <xsd:annotation>
                        <xsd:documentation xml:lang="en">Affirmation
regarding signature on written receipt. A one character (Y = Yes, N = No) data element which
affirms that the manufacturer or distributor has the signature on file for the sample receipt. This
has been included to avoid placing a burden on firms who would otherwise need to send in an
```

```xml
image of the signature.</xsd:documentation>
                              </xsd:annotation>
                         </xsd:element>
                    </xsd:sequence>
          </xsd:group>
          <xsd:complexType name="Business">
                    <xsd:sequence>
                         <xsd:element name="businessType" type="tns:BusinessType"/>
                         <xsd:element name="businessName">
                              <xsd:annotation>
                                   <xsd:documentation xml:lang="en">The business name
of the manufacturer or distributor of the firm which distributed the
sample.</xsd:documentation>
                              </xsd:annotation>
                              <xsd:simpleType>
                                   <xsd:restriction base="xsd:string">
                                        <xsd:minLength value="1"/>
                                        <xsd:maxLength value="300"/>
                                        <xsd:whiteSpace value="collapse"/>
                                   </xsd:restriction>
                              </xsd:simpleType>
                         </xsd:element>
                         <!--
          <xsd:element name="businessDUNS">
             <xsd:annotation>
               <xsd:documentation xml:lang="en">Reserved for future use. The DUNS number
being requested is the corporate DUNS number. Unique Identifier for
firms</xsd:documentation>
             </xsd:annotation>
             <xsd:simpleType>
               <xsd:restriction base="xsd:string">
                  <xsd:minLength value="1"/>
                  <xsd:maxLength value="50"/>
                  <xsd:whiteSpace value="collapse"/>
               </xsd:restriction>
             </xsd:simpleType>
          </xsd:element>
          -->
                    </xsd:sequence>
          </xsd:complexType>
          <xsd:simpleType name="BusinessType">
                    <xsd:restriction base="xsd:string">
                         <xsd:enumeration value="Manufacturer"/>
                         <xsd:enumeration value="Distributor"/>
                    </xsd:restriction>
```

```xml
        </xsd:simpleType>
        <xsd:simpleType name="AffirmationSignatureType">
                <xsd:restriction base="xsd:string">
                        <xsd:enumeration value="Y"/>
                        <xsd:enumeration value="N"/>
                </xsd:restriction>
        </xsd:simpleType>
        <xsd:complexType name="PractitionerType">
                <xsd:sequence>
                        <!--
<xsd:element name="NPINumber">
   <xsd:annotation>
        <xsd:documentation xml:lang="en">Reserved for future use. National Provider
Identifier (NPI). Unique Identifier for providers</xsd:documentation>
        </xsd:annotation>
        <xsd:simpleType>
           <xsd:restriction base="xsd:string">
              <xsd:minLength value="1"/>
              <xsd:maxLength value="50"/>
              <xsd:whiteSpace value="collapse"/>
           </xsd:restriction>
        </xsd:simpleType>
   </xsd:element>
   -->
                        <xsd:element name="practitionerDesignation"
type="tns:PractitionerDesignationType"/>
                        <xsd:element name="person" type="tns:PersonType"/>
                        <xsd:element name="personAddress" type="tns:USAddress"/>
                </xsd:sequence>
        </xsd:complexType>
        <xsd:complexType name="DesigneeType">
                <xsd:sequence>
                        <xsd:element name="person" type="tns:PersonType"/>
                        <xsd:element name="personAddress" type="tns:USAddress"
minOccurs="0"/>
                </xsd:sequence>
        </xsd:complexType>
        <xsd:complexType name="PersonType">
                <xsd:sequence>
                        <xsd:element name="firstName">
                                <xsd:simpleType>
                                        <xsd:restriction base="xsd:string">
                                                <xsd:minLength value="1"/>
                                                <xsd:maxLength value="50"/>
                                                <xsd:whiteSpace value="collapse"/>
```

```xml
                        </xsd:restriction>
                    </xsd:simpleType>
                </xsd:element>
                <xsd:element name="lastName">
                    <xsd:simpleType>
                        <xsd:restriction base="xsd:string">
                            <xsd:minLength value="1"/>
                            <xsd:maxLength value="50"/>
                            <xsd:whiteSpace value="collapse"/>
                        </xsd:restriction>
                    </xsd:simpleType>
                </xsd:element>
                <xsd:element name="middleInitial" minOccurs="0">
                    <xsd:simpleType>
                        <xsd:restriction base="xsd:string">
                            <xsd:maxLength value="1"/>
                            <xsd:whiteSpace value="collapse"/>
                        </xsd:restriction>
                    </xsd:simpleType>
                </xsd:element>
            </xsd:sequence>
        </xsd:complexType>
        <xsd:complexType name="USAddress">
            <xsd:sequence>
                <xsd:element name="addressLine1">
                    <xsd:simpleType>
                        <xsd:restriction base="xsd:string">
                            <xsd:minLength value="1"/>
                            <xsd:maxLength value="150"/>
                            <xsd:whiteSpace value="collapse"/>
                        </xsd:restriction>
                    </xsd:simpleType>
                </xsd:element>
                <xsd:element name="addressLine2" minOccurs="0">
                    <xsd:simpleType>
                        <xsd:restriction base="xsd:string">
                            <xsd:maxLength value="150"/>
                            <xsd:whiteSpace value="collapse"/>
                        </xsd:restriction>
                    </xsd:simpleType>
                </xsd:element>
                <xsd:element name="city">
                    <xsd:simpleType>
                        <xsd:restriction base="xsd:string">
                            <xsd:minLength value="1"/>
```

```xml
                                    <xsd:maxLength value="50"/>
                                    <xsd:whiteSpace value="collapse"/>
                            </xsd:restriction>
                    </xsd:simpleType>
            </xsd:element>
            <xsd:element name="state" type="tns:StateType"/>
            <xsd:element name="zip">
                    <xsd:simpleType>
                            <xsd:restriction base="xsd:string">
                                    <xsd:pattern value="\s*\d{5}([\-]\d{4})?\s*"/>
                            </xsd:restriction>
                    </xsd:simpleType>
            </xsd:element>
        </xsd:sequence>
</xsd:complexType>
<xsd:simpleType name="StateType">
        <xsd:restriction base="xsd:string">
                <xsd:enumeration value="AL"/>
                <xsd:enumeration value="AK"/>
                <xsd:enumeration value="AS"/>
                <xsd:enumeration value="AZ"/>
                <xsd:enumeration value="AR"/>
                <xsd:enumeration value="CA"/>
                <xsd:enumeration value="CO"/>
                <xsd:enumeration value="CT"/>
                <xsd:enumeration value="DE"/>
                <xsd:enumeration value="DC"/>
                <xsd:enumeration value="FM"/>
                <xsd:enumeration value="FL"/>
                <xsd:enumeration value="GA"/>
                <xsd:enumeration value="GU"/>
                <xsd:enumeration value="HI"/>
                <xsd:enumeration value="ID"/>
                <xsd:enumeration value="IL"/>
                <xsd:enumeration value="IN"/>
                <xsd:enumeration value="IA"/>
                <xsd:enumeration value="KS"/>
                <xsd:enumeration value="KY"/>
                <xsd:enumeration value="LA"/>
                <xsd:enumeration value="ME"/>
                <xsd:enumeration value="MH"/>
                <xsd:enumeration value="MD"/>
                <xsd:enumeration value="MA"/>
                <xsd:enumeration value="MI"/>
                <xsd:enumeration value="MN"/>
```

```
                    <xsd:enumeration value="MS"/>
                    <xsd:enumeration value="MO"/>
                    <xsd:enumeration value="MT"/>
                    <xsd:enumeration value="NE"/>
                    <xsd:enumeration value="NV"/>
                    <xsd:enumeration value="NH"/>
                    <xsd:enumeration value="NJ"/>
                    <xsd:enumeration value="NM"/>
                    <xsd:enumeration value="NY"/>
                    <xsd:enumeration value="NC"/>
                    <xsd:enumeration value="ND"/>
                    <xsd:enumeration value="MP"/>
                    <xsd:enumeration value="OH"/>
                    <xsd:enumeration value="OK"/>
                    <xsd:enumeration value="OR"/>
                    <xsd:enumeration value="PW"/>
                    <xsd:enumeration value="PA"/>
                    <xsd:enumeration value="PR"/>
                    <xsd:enumeration value="RI"/>
                    <xsd:enumeration value="SC"/>
                    <xsd:enumeration value="SD"/>
                    <xsd:enumeration value="TN"/>
                    <xsd:enumeration value="TX"/>
                    <xsd:enumeration value="UM"/>
                    <xsd:enumeration value="VI"/>
                    <xsd:enumeration value="UT"/>
                    <xsd:enumeration value="VT"/>
                    <xsd:enumeration value="VA"/>
                    <xsd:enumeration value="WA"/>
                    <xsd:enumeration value="WV"/>
                    <xsd:enumeration value="WI"/>
                    <xsd:enumeration value="WY"/>
                </xsd:restriction>
        </xsd:simpleType>
        <xsd:simpleType name="PractitionerDesignationType">
                <xsd:restriction base="xsd:string">
                        <xsd:enumeration value="AAP"/>
                        <xsd:enumeration value="ABAI"/>
                        <xsd:enumeration value="ABFP"/>
                        <xsd:enumeration value="ABO"/>
                        <xsd:enumeration value="ABPN"/>
                        <xsd:enumeration value="AK"/>
                        <xsd:enumeration value="AOBFP"/>
                        <xsd:enumeration value="AOBSPOMM"/>
                        <xsd:enumeration value="AP"/>
```

```
<xsd:enumeration value="ASG"/>
<xsd:enumeration value="BHMS"/>
<xsd:enumeration value="BSN"/>
<xsd:enumeration value="BVScAH"/>
<xsd:enumeration value="CA"/>
<xsd:enumeration value="CAAPM"/>
<xsd:enumeration value="CAC"/>
<xsd:enumeration value="CCH"/>
<xsd:enumeration value="CCSP"/>
<xsd:enumeration value="CRNP"/>
<xsd:enumeration value="CRRN"/>
<xsd:enumeration value="CSPOMM"/>
<xsd:enumeration value="CVA"/>
<xsd:enumeration value="DAAPM"/>
<xsd:enumeration value="DABFP"/>
<xsd:enumeration value="DABIM"/>
<xsd:enumeration value="DAc"/>
<xsd:enumeration value="DAc (RI)"/>
<xsd:enumeration value="DAc (WV)"/>
<xsd:enumeration value="DACBN"/>
<xsd:enumeration value="DACVD"/>
<xsd:enumeration value="DC"/>
<xsd:enumeration value="DDS"/>
<xsd:enumeration value="DHANP"/>
<xsd:enumeration value="DHt"/>
<xsd:enumeration value="DMD"/>
<xsd:enumeration value="DNBHE"/>
<xsd:enumeration value="DO"/>
<xsd:enumeration value="DOM"/>
<xsd:enumeration value="DPM"/>
<xsd:enumeration value="DVM"/>
<xsd:enumeration value="FAAEM"/>
<xsd:enumeration value="FAAFP"/>
<xsd:enumeration value="FAAP"/>
<xsd:enumeration value="FACFO"/>
<xsd:enumeration value="FACOG"/>
<xsd:enumeration value="FAGD"/>
<xsd:enumeration value="FIACA"/>
<xsd:enumeration value="FIAOMT"/>
<xsd:enumeration value="FICCMO"/>
<xsd:enumeration value="FNP"/>
<xsd:enumeration value="HASG"/>
<xsd:enumeration value="HLL"/>
<xsd:enumeration value="HMD"/>
<xsd:enumeration value="HSG"/>
```

```xml
                        <xsd:enumeration value="LAc"/>
                        <xsd:enumeration value="LicAc"/>
                        <xsd:enumeration value="LL"/>
                        <xsd:enumeration value="LN"/>
                        <xsd:enumeration value="LNC"/>
                        <xsd:enumeration value="MD"/>
                        <xsd:enumeration value="MD(H)"/>
                        <xsd:enumeration value="MFCC"/>
                        <xsd:enumeration value="MNNP"/>
                        <xsd:enumeration value="MPH"/>
                        <xsd:enumeration value="MSN"/>
                        <xsd:enumeration value="MSW"/>
                        <xsd:enumeration value="NCCA"/>
                        <xsd:enumeration value="ND"/>
                        <xsd:enumeration value="NMD"/>
                        <xsd:enumeration value="NP"/>
                        <xsd:enumeration value="OD"/>
                        <xsd:enumeration value="OMD"/>
                        <xsd:enumeration value="PA"/>
                        <xsd:enumeration value="PA-C"/>
                        <xsd:enumeration value="PhD"/>
                        <xsd:enumeration value="PsyD"/>
                        <xsd:enumeration value="PT"/>
                        <xsd:enumeration value="RN"/>
                        <xsd:enumeration value="RN/NP"/>
                        <xsd:enumeration value="RN-C"/>
                        <xsd:enumeration value="RNCS"/>
                        <xsd:enumeration value="RPh"/>
                        <xsd:enumeration value="RS Hom"/>
                        <xsd:enumeration value="SG"/>
                        <xsd:enumeration value="VMD"/>
                        <xsd:enumeration value="Other"/>
                </xsd:restriction>
        </xsd:simpleType>
</xsd:schema>
```

Appendix 2 ACA 6004 Data Element Definitions

Element Name	Data Type(Size)	Definition
submissionYear	VARCHAR2(4)	This is the calendar year the sample being reported was distributed to the practitioner/recipient
businessType	VARCHAR2(12)	The business firm will select one of the following provided values: • Manufacturer • Distributor
businessName	VARCHAR2(300)	The business name of the manufacturer or distributor of the firm which distributed the sample
practitionerDesignation	VARCHAR2(10)	This is the professional title of the practitioner, e.g. MD, PA, etc...
firstName	VARCHAR2(50)	The first name of the practitioner or the practitioner designee.
middleInitial	VARCHAR2(1)	The middle initial of the practitioner or the practitioner designee.
lastName	VARCHAR2(50)	The last name of the practitioner or the practitioner designee.
addressLine1	VARCHAR2(150)	Line 1 of the standard address - street number, street, Suite or room number.
addressLine2	VARCHAR2(150)	Line 2 of the standard address - street number, street, Suite or room number.
city	VARCHAR2(50)	The US city name.
state	VARCHAR2(2)	The 2 letter abbreviation for the US states.

zip	VARCHAR2(10)	The US ZIP code in the format of 12345-6789.
tradeNameDosage	VARCHAR2(100)	This refers to the trade name and dosage of the sample distributed. For example, "Synthroid 0.1mg".
pkgSize	VARCHAR2(100)	A description of the size and type of packaging in sentence form. For example: 4 BOTTLES in 1 CARTON/100 TABLETS in 1 BOTTLE.
pkgQtyReq	VARCHAR2(100)	This is the total quantity of packages of the drug (trade name and dosage) requested during the calendar year. This should be aggregated by the practitioner who signed for the sample request.
pkgQtyDist	VARCHAR2(100)	This is the total quantity of packages of the drug (trade name and dosage) distributed during the calendar year. This should be aggregated by the practitioner *or the recipient* who signed for the sample distribution.
hasReqSignature	VARCHAR2(1)	Affirmation regarding signature on written request. A one character (Y = Yes, N = No) data element which affirms that the manufacturer or distributor has the signature on file for the sample request.
hasReceiptSignature	VARCHAR2(1)	Affirmation regarding signature on written request. A one character (Y = Yes, N = No) data element which affirms that the manufacturer or distributor has the signature on file for the sample receipt.