ACA Section 6004 Submissions FREQUENTLY ASKED QUESTIONS (FAQ)

Q1: We are in the process of executing the final xml extract, but I am concerned by the language in the Draft Guidance around the Agency issuing further draft guidance this year. Do you have any idea if this would impact the schema and data elements that we are currently working with? Or is the technical guidance complete as posted?

A1: The agency currently has no plans to change the schema for this reporting year (2012), and intends to provide notice of any significant changes well in advance. It is our intent to keep current technical information and guidance available on our website.

Q2: In our data there were a few instances where the value for *practitioner Designation* field was missing, we are addressing this data issue. Is this field okay to be blank until a fix is in place?

A2: You can populate the element with "Other". The Practitioner designation (Title) element is mandatory and should contain values from the list in the FDA XML schema. The value "Other" is on the list in the FDA XML schema.

Q3: We have a practitioner whose designation is not listed in the Practitioner Acronym Table?

A3: If you have practitioner whose designation is not listed on the Practitioner Acronym table, then you can substitute "Other".

Q4: What do we do if we have special characters in the report? During the initial development, our technical team had challenges inputting records that contained an "&" in the xml element value. Does the FDA want us to keep the "&" in our records or should we replace it with a similar meaningful value like 'and'. This "&' is also present in the address line field.

A4: Please use 'and' in your submission, in place of the ampersand, at least for the moment. Special characters are not currently supported by the ACA schema. Therefore, the following special characters **or** their escape symbols will not pass validation. FDA is reviewing the level of effort required to update the schema to handle the escape special character symbols below and will notify industry when this feature can be made available.

Special character	Escape symbols
&	&amp;

>	>
<	<
‘	'
“	"

Q5: Does the order of the data elements in the xml file matter?

A5: Yes, order matters. Please be sure to follow the FDA XML schema available on the ACA 6004 webpage: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm

Q6: Can we submit a file that has missing data? Or data in the wrong fields?

A6: The data should conform to the specification represented in the schema. Invalid files will be rejected and you will need to correct the submission and resubmit. We strongly recommend you always validate your submission against the FDA XML schema using any XML validator before submitting it through the gateway.

Q7: Who do I contact to set up a Gateway account?

A7: For accounts or questions, please contact the FDA Electronic Submissions Gateway Help Desk at esgreg@gnsi.com. Additional information is available on the FDA Website at http://www.fda.gov/esg

Q8: Do I need a new gateway account or can I use an existing gateway account for ACA 6004 submissions?

A8: You do not need a new gateway account for the ACA 6004 submissions if you have an existing account.

Q9: Is there any specific file naming convention we should use?

A9: Yes, 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.

Q10: Should I submit individual files or folders and what is the limitation on the size of files and folders?

A10: All files must be submitted within a folder (each submission folder shall contain one or more XML files). Each individual file within folders must be smaller than or equal to 200MB.Total folder size may exceed 200MB but must not exceed 2GB in size.

Q11: What type of files should be submitted?

A11: All files must be in XML format and must be validated against the FDA-provided XML schema before submission. Each XML file's name must have an .xml extension and must conform to the naming convention described above.

Q12: Do you have a Web based validator that we can check our submissions with?

A12: We do not have a web based validator. We recommend that you use an XML editor to validate your submissions against the FDA XML schema before you send them to us.

Q13: What is the web site where I can get all the information?

A13: The web address where you can get all the information is:

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm

Q14: Where is the guidance located?

A14:

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM297848.pdf

Q15: What is the email address where I can send questions?

A15: For questions concerning the gateway: esgreg@gnsi.com

For all other questions: cder_obi_aca6004@fda.hhs.gov