

eCTD Validation

November 7, 2008

Constance Robinson-Kuiperi, RAC, PMP

FDA\CDER\OBPS\DRRS

November 7, 2008

eCTD Validation – what exactly are we talking about?

- Gateway Validation
- ASR Validation
- eCTD Tool Validation
- Qualitative Validation

Validation Flow

Gateway Validation

ASR Validation

eCTD Tool Validation

Division Quality Checks

Gateway Validation

- Once you have established an account this is almost never an issue
- The Gateway Validation is concerned with file integrity

Automated Submission Receipt (ASR)

- **ASR**
 - Processes your submission
 - Looks for consistency between us-regional and form
 - Loads the submission into CDER's tracking system
 - Notifies the Regulatory Project Manager
- **To operate efficiently we need**
 - eCTD
 - Fillable Form 1571/356h
 - Accurate Information, e.g., application number, us-regional.xml

eCTD Tool Validation

- Identifies and rates the severity of the errors encountered
 - High Errors vs. Medium Errors vs. Low errors
- The criteria for these have been published:
 - http://www.fda.gov/cder/regulatory/ersr/validation_specs.htm

Division Quality Checks

- Hyperlinks/Bookmarks
- Datasets
- Table of Contents Issues
- Missing Files

The Top Validation Issues

- Lack of 356h, 1571, or 2252
- No Fillable Forms
- More than one form in a submission

The Top Validation Issues

contd.

- Mismatched application number between the us-regional.xml and the form
- Incorrect, missing or no application number - either on the form or in the us-regional.xml
- Invalid submission identified - ex. eCTD submitted as eNDA
- Bad Characters in file or folder names

The Top Validation Issues

contd.

- More than one sequence included in one gateway submission
- One submission applied to more than one application
- Single file submission – Usually a single PDF file
- Mismatch between application type and form - an NDA with a 1571.PDF

Why do you care

- These errors require us to manually process your gateway submission
- Manually processed submissions delay access to your material
- More hands in the pot increases chances for error
- Your submission could be returned

How to avoid problems



Include a form - 356h, 1571, or 2252



- The information assists us in processing your submission
- If you are using the Gateway it is extremely helpful to have a form
- If you use the Gateway and you aren't required by regulations to send in a form – send in a form – just don't sign it

Use a Fillable PDF form

- Fillable forms allow us to extract the data necessary to automatically process your submission
- Using a scanned form will delay processing
- <http://www.fda.gov/opacom/morechoices/fdaforms/cder.htm>



One form is enough – don't send in more than one form in a submission



- Our ASR program looks for the “356h” in 356h.PDF
- 356h-append.PDF looks like another 356h.pdf to our program.
- If you need to send another form name it form-addendum.pdf, signed-form.pdf

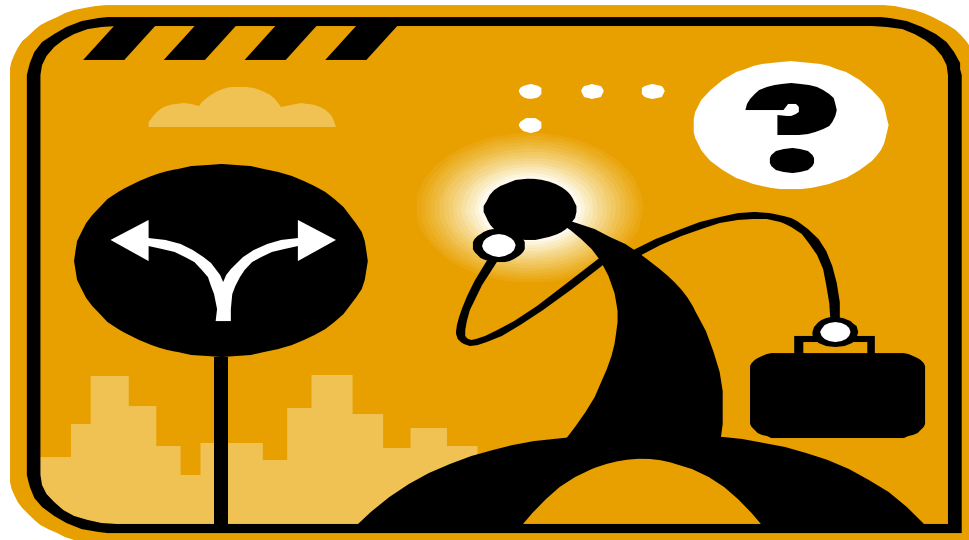
PDF Form and us-regional.XML Mismatch

- The form has your application number
- The us-regional.XML has your application number
- They need to be the same number
- It's fine to reuse XML – just clean it up first



Invalid submission type

- eNDA submission going to an eCTD application

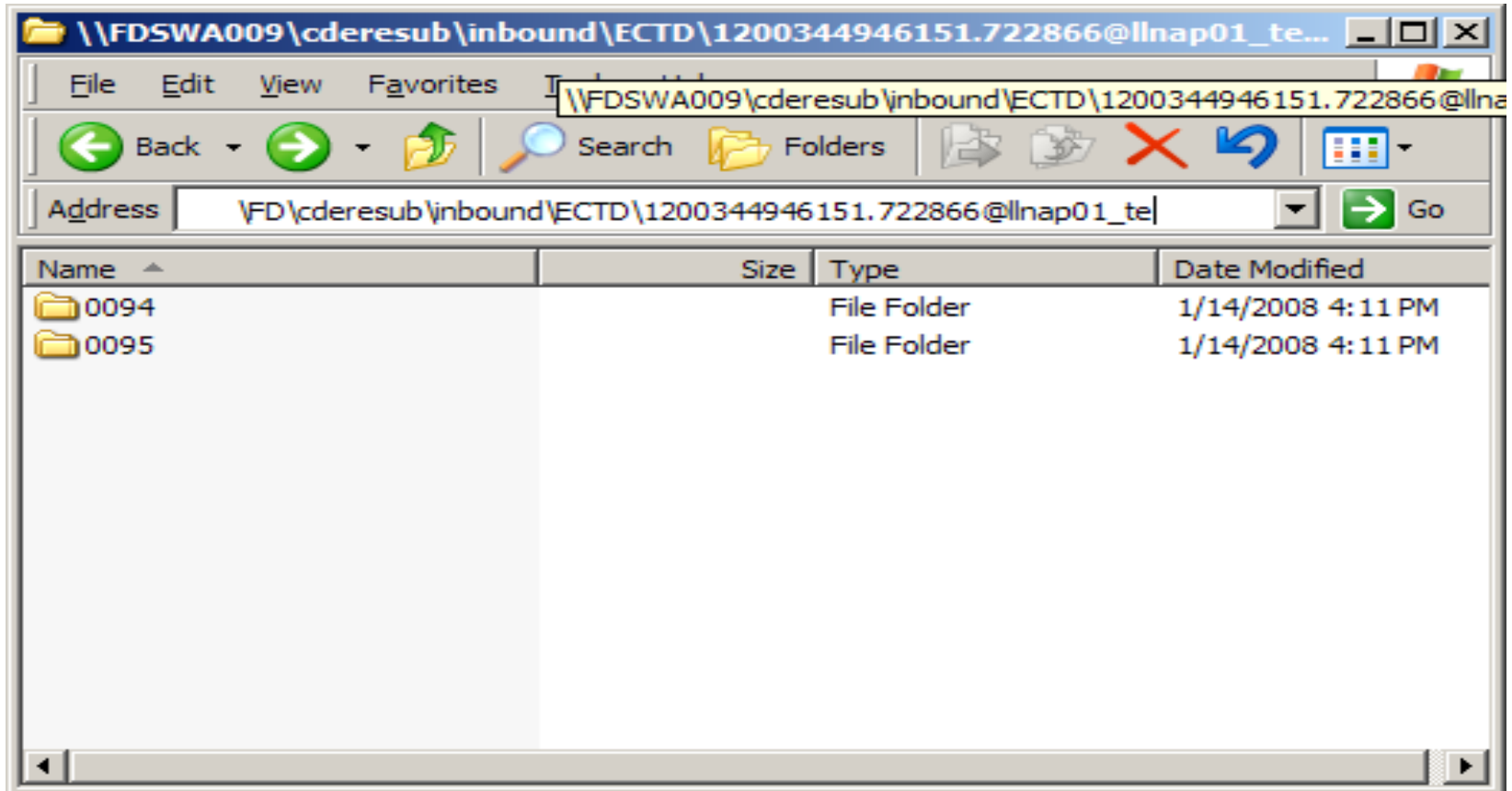


Bad Characters in the file or folder names

- Using *spaces* in folder or file names is not recommended – use a hyphen or underscore
- Other illegal characters:
 - / - forward slash
 - \ - backslash
 - : - colon
 - ? - question mark
 - “ - quotation marks
 - < - less than sign
 - > - greater than sign
 - | - vertical bar,



Please send in one Sequence per transaction – please be sure that one sequence is correct



Please do not send in one submission to be applied to multiple applications



- When working with the eCTD this will not work
- One submission should contain one sequence for one application

Single File Submission

- Usually a single PDF file
- Gateway submissions to be processed automatically must have the proper fillable forms



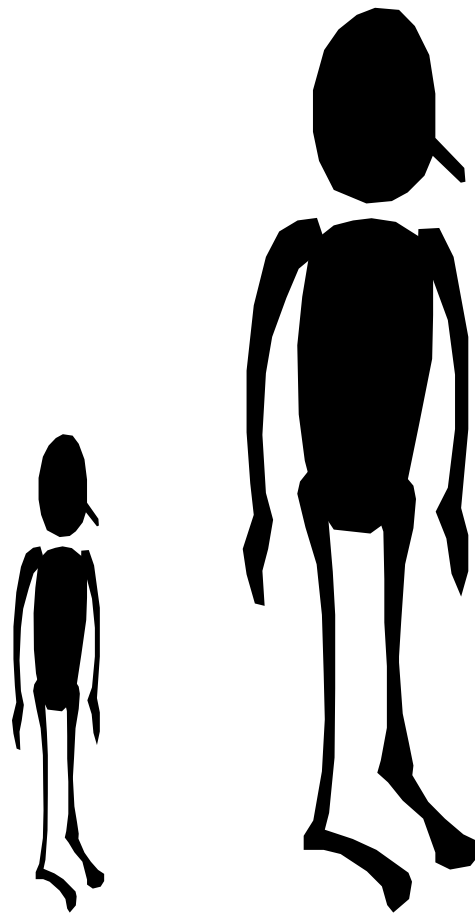
Incorrect or Missing Application Number on the form or US-Regional

- We want your submission to go to the right place
- If the number is missing or nonexistent or incorrect – we can't automatically process it
- Before you use the Gateway – get a pre-assigned application number first

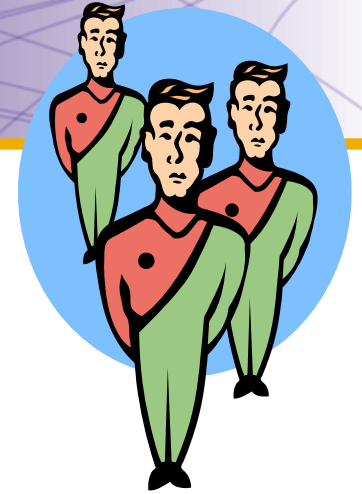


Mismatch between application type and form

- NDA with a 1571.PDF
- IND with a 356h.PDF



Duplicate Submissions Duplicate Submissions



- Once is enough
- We only process the first submission not the duplicate
- If the first submission was in error contact esub@fda.hhs.gov

Naming Forms

- Use the form number as the file name
 - 1571.pdf for the for INDs
 - 356h.pdf for the NDAs
 - 2252.pdf for the Annual Reports
 - 3674.pdf for the Certification of Compliance
- If you need a continuation sheet consider name such as application-form-addendum that don't include the form number.

Final Thoughts

- Helpful to have a Technical Contact listed in your cover letter with an email and phone number
- Name your high level folder your 4 digit sequence number when eCTD
- Application numbers are 6 digits

**Still have questions?
Relax and send us an email:
esub@fda.hhs.gov**

