

**Addendum to the
eCTD Backbone Files Specification For Module 1
Version 2.3, 07/01/2014**

The following additional information is being provided to support modifications to leaf(s) in grouped submissions. When a leaf from a previous grouped submission is being updated using eCTD operator attributes: replace, delete, or append; the modified file path of the leaf in the us-regional.xml needs to include the application type prefix with the application number in order for the link to be valid. An example is shown below and on the top of page 16 in [the eCTD Backbone Files Specification for Module 1 Version 2.3](#).

Example:

```
...  
modified-file=" ../../../../nda456789/0001/m1/us/us-regional.xml#id21342"  
...
```

The prefixes used for applications stored on FDA servers are shown in the table below:

Prefix	Application Type(s)	Centers*
nda	New Drug Application	CDER
ind	Investigational New Drug	CDER
anda	Abbreviated New Drug Application	CDER
mf	Drug Master File (DMF) and Biologics Master File (BMF)	CDER
bla	Biologic License Application	CDER and CBER

*Note: Center information provided in the table above follows limitations and use from table 7 in [the eCTD Backbone Files Specification for Module 1 Version 2.3](#)

For more information about modifying leaf(s) in grouped submissions and limitations and use in grouped submissions, please refer to pages 13 and 16 in [the eCTD Backbone Files Specification for Module 1 Version 2.3](#).