

Addendum 2 to the eCTD Backbone Files Specification For Module 1 Version 2.3, 04/01/2015

The following additional information is being provided to support grouped submissions, specifically grouped submissions to 2 different regulatory activities in the same application. Example #27: Amendment to 2 Efficacy supplements in the same application is being amended to indicate only the <application> element where application-containing-files = "true" should contain a transmittal form. It is not necessary to reference the same form twice or separate forms since both submissions are being sent to a single application.

The amended <application-set> now indicates:

```
<application-set>
  <application application-containing-files="true">
    <application-information>
      <!-- application-type "fdaat1" is NDA -->
      <application-number application-type="fdaat1">987654</application-number>
    </application-information>
    <submission-information>
      <!-- submission-type "fdast2" is efficacy supplement-->
      <submission-id submission-type="fdast2">0010</submission-id>
      <!-- submission-sub-type "fdasst4" is amendment -->
      <sequence-number submission-sub-type="fdasst4">0020</sequence-number>
      <!-- form-type "fdaft2" is Form FDA 356h -->
      <form form-type="fdaft2">
        <leaf ID="a11383b1215534dfd8a81df05237f608"
checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5" operation="new" xlink:href="356h-
0020.pdf" xlink:type="simple">
          <title>Form FDA 356h 0020 Amendment</title>
        </leaf>
      </form>
    </submission-information>
  </application>
  <application application-containing-files="false">
    <application-information>
      <!-- application-type "fdaat1" is NDA -->
      <application-number application-type="fdaat1">987654</application-number>
    </application-information>
    <submission-information>
      <!-- submission-type "fdast2" is efficacy supplement-->
      <submission-id submission-type="fdast2">0015</submission-id>
      <!-- submission-sub-type "fdasst4" is amendment -->
      <sequence-number submission-sub-type="fdasst4">0020</sequence-number>
    </submission-information>
  </application>
</application-set>
```