Example Submissions using the eCTD Backbone Files Specification for Module 1

Example Submissions using the eCTD Backbone Files Specification for Module 1

Revision History

Date	Version	Summary of Changes
2012-06-01	1.0	Original version
2012-11-01	1.1	Modified DTD version references to reflect 3.1 instead of 3.0
2013-08-23	1.2	Modified example 7 to reference the Form FDA 356h in the Admin section. Modified examples 13 through 17 to reference the material-id and issue date attributes, as applicable, and include the Promotional Labeling and Advertising Regulatory Contact. Modified DTD version references to reflect 3.2 instead of 3.1
2014-02-07	1.3	Replaced DTD version 3.2 references with version 3.3.
2015-04-01	1.4	Modified example 27 to remove the Form FDA 356h reference from the 2nd application in the application set. For grouped submissions to the same application, the form should only be referenced once, in the application where application-containing-files = “True”.

Example Submissions using the eCTD Backbone Files Specification for Module 1

TABLE OF CONTENTS

Example Submissions using the eCTD Backbone Files Specification for Module 1 1
TABLE OF CONTENTS 1
Examples of Various Submissions and the XML Code in the us-regional.xml 2
Introduction 2
Example #1: Presubmission to an NDA Original Application 2
Example #2: Presubmission to an NDA Original Application 4
Example #3: An NDA Original Application 6
Example #4: Amendment #1 to an NDA Original Application 8
Example #5: Amendment #2 to an NDA Original Application 10
Example #6: NDA Efficacy Supplement (new indication) 12
Example #7: NDA Annual Report 14
Example #8: Amendment #1 to an NDA Efficacy Supplement 16
Example #9: NDA Labeling Supplement CBE-0 17
Example #10: Amendment #2 to an NDA Efficacy Supplement 19
Example #11: Grouped NDA Labeling Supplement 21
Example #12: Amendment to a Grouped NDA Labeling Supplement 24
Example #13: Promotional Labeling Advertising (Request for Advisory - Launch Materials) 27
Example #14: Resubmission of a Promotional Labeling Advertising Submission 31
Example #15: Promotional - Withdrawal Request for Launch Advisory 34
Example #16: Promotional Labeling-Advertising - 2253 submission 37
Example #17: Grouped Promotional Submission (2253 Submission) 39
Example #18: Presubmission to a Rolling BLA 42
Example #19: Presubmission to a Rolling BLA 44
Example #20: Original Application to a Rolling BLA 46
Example #21: Initial IND 48
Example #22: IND – IND Protocol Amendment 50
Example #23: IND – Initial Safety Report 51
Example #24: IND – Safety Report Follow-up #1 53
Example #25: Grouped Submission: DSUR to Multiple IND Applications 55
Example #26: IND Meeting Request 58
Example #27: Amendment to 2 Efficacy supplements in the same application 60
Examples - Transitioning from DTD Version 2.01 to DTD Version 3.3 63
Example #28a: Legacy - Last amendment submitted using the old DTD Version 2.01 63
Example #28b: 120-day Safety Update to a legacy application using the new DTD Version 3.3: 64
Example #29a: Legacy - Original-application submitted using the old DTD Version 2.01: .. 66
Example #29b: Amendment to a legacy application using the new DTD Version 3.3: 67

Examples of Various Submissions and the XML Code in the us-regional.xml

Introduction

The purpose of this document is to provide examples showing the changes to admin section of submissions using DTD version 3.3. The examples are not intended to be used as templates for content.

Example #1: Presubmission to an NDA Original Application

```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Pre-NDA Meeting Request</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3 is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                </telephones>
                <emails>
                    <email>jane.smith@gooddrugs.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
```

```
                <email>john.smith@gooddrugs.com</email>
            </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

        <application-set>
            <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                    <application-number application-type="fdaat1">456789</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast1" is original-application -->
                    <submission-id submission-type="fdast1">0001</submission-id>
                <!-- submission-sub-type "fdasst2" is presubmission -->
                    <sequence-number submission-sub-type="fdasst2">0001</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0001.pdf" xlink:type="simple">
                        <title>Form FDA 356h - NDA 456789 - Meeting Request</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0001.pdf" xlink:type="simple">
            <title>Cover Letter - NDA 456789 - Pre-NDA Meeting Request</title>
        </leaf>
    </m1-2-cover-letters>
    <m1-6-meetings>
        <m1-6-1-meeting-request>
            <leaf ID="a11383b1215534dfmi9a98bf05237f794" checksum="49e154b9bee083a2de61m459affd63e3" checksum-type="md5"
operation="new" xlink:href="meeting-request.pdf" xlink:type="simple">
```

```
                <title>Pre-NDA Meeting Request</title>
            </leaf>
        </m1-6-1-meeting-request>
    </m1-6-meetings>
</m1-regional>
</fda-regional:fda-regional>
```


Example #2: Presubmission to an NDA Original Application


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Pre-NDA Briefing Package</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                </telephones>
                <emails>
                    <email>jane.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
```

```
                <email>john.smith@gooddrugs.com</email>
            </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">456789</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast1" is original-application -->
                <submission-id submission-type="fdast1">0001</submission-id>
                <!-- submission-sub-type "fdasst2" is presubmission -->
                <sequence-number submission-sub-type="fdasst2">0002</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0002.pdf" xlink:type="simple">
                        <title>Form FDA 356h - NDA 456789 - Briefing Package</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0002.pdf" xlink:type="simple">
            <title>Cover Letter - NDA 456789 - Pre-NDA Meeting Briefing Package</title>
        </leaf>
    </m1-2-cover-letters>

    <m1-6-meetings>
        <m1-6-2-meeting-background-materials>
```

```
                <leaf ID="a11383b1215534dfdf8a98bf05237f794" checksum="49e154b9bee083a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="briefing-package.pdf" xlink:type="simple">
                        <title>Pre-NDA Meeting Briefing Package</title>
                </leaf>
            </m1-6-2-meeting-background-materials>
        </m1-6-meetings>
</m1-regional>
</fda-regional:fda-regional>
```


Example #3: An NDA Original Application


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
   <applicant-info>
      <id>123456789</id>
      <company-name>Good Drugs</company-name>
            <submission-description>Original Application - Indication: pain</submission-description>
      <applicant-contacts>
                <applicant-contact>
                        <!--applicant-contact-type "fdaact1" is regulatory -->
                        <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                        <telephones>
                                <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3 is mobile-telephone -->
                                <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                                <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                        </telephones>
                        <emails>
                                <email>jane.smith@gooddrugs.com</email>
                        </emails>
         </applicant-contact>
                <applicant-contact>
                        <!-- applicant-contact-type "fdaact2" is technical -->
                        <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                        <telephones>
                                <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                                <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                        </telephones>
```

```
                <emails>
                    <email>john.smith@gooddrugs.com</email>
                </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

        <application-set>
            <application application-containing-files="true">
                <application-information>
                    <!-- application-type "fdaat1" is NDA -->
                    <application-number application-type="fdaat1">456789</application-number>
                    <!-- application-type "fdaat5" is DMF -->
                    <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
                    <cross-reference-application-number application-type="fdaat5">543210</cross-reference-application-number>
                </application-information>
                <submission-information>
                    <!-- submission-type "fdast1" is original-application -->
                    <submission-id submission-type="fdast1">0001</submission-id>
                    <!-- submission-sub-type "fdasst3" is application -->
                    <sequence-number submission-sub-type="fdasst3">0003</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
                    <form form-type="fdaft2">
                        <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0003.pdf" xlink:type="simple">
                            <title>Form FDA 356h - NDA 456789 - Original Application</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0003.pdf" xlink:type="simple">
                <title>Cover Letter - NDA 456789 - Original Application - Indication: pain</title>
            </leaf>
```

```
        <leaf ID="a11383b1215697dfdf8a81df05237f794" checksum="49e154b9bee284a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="reviewers-guide.pdf" xlink:type="simple">
            <title>Reviewers Guide - Original Application</title>
        </leaf>
    </m1-2-cover-letters>
    <m1-4-references>
    <m1-4-2-statement-of-right-of-reference>
        <leaf ID="a11383b1215697dfdf8a81df05237f664" checksum="49e154b9bee284a2de43c459affd22e3" checksum-type="md5" operation="new"
xlink:href="dmf012345-stopper.pdf" xlink:type="simple">
            <title>DMF 012345 stopper - Company ABC</title>
        </leaf>
            <leaf ID="a11383b1215697dfdf8a81df05237f194" checksum="49e154b9bee284a2de43c459affd21e3" checksum-type="md5" operation="new"
xlink:href="dmf-543210-vial.pdf" xlink:type="simple">
            <title>DMF 543210 vial - Company BCD</title>
        </leaf>
    </m1-4-2-statement-of-right-of-reference>
    </m1-4-references>
</m1-regional>
</fda-regional:fda-regional>
```


Example #4: Amendment #1 to an NDA Original Application


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Amendment - Additional datasets for Study xyz</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                </telephones>
```

```
                <emails>
                    <email>jane.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                    <telephones>
                        <telephone telephone-number-type="fdatbt1">1-212-555-1213</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
                    <email>john.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">456789</application-number>
                <!-- application-type "fdaat5" is DMF -->
                <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
                </application-information>
            <submission-information>
                <!-- submission-type "fdast1" is original-application -->
                <submission-id submission-type="fdast1">0001</submission-id>
                <!-- submission-sub-type "fdasst4" is amendment -->
                <sequence-number submission-sub-type="fdasst4">0004</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0004.pdf" xlink:type="simple">
                        <title>Form FDA 356h - 0004 - Additional datasets</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
```

```
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0004.pdf" xlink:type="simple">
            <title>Cover Letter - NDA 456789 - Additional datasets</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #5: Amendment #2 to an NDA Original Application


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Amendment - Response to Information Request dated 06-30-2011</submission-description>
         <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                </telephones>
                <emails>
                    <email>jane.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
```

```
                    <telephones>
                        <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                    </telephones>
                    <emails>
                        <email>john.smith@gooddrugs.com</email>
                    </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

        <application-set>
            <application application-containing-files="true">
                <application-information>
                    <!-- application-type "fdaat1" is NDA -->
                    <application-number application-type="fdaat1">456789</application-number>
                    <!-- application-type "fdaat5" is DMF -->
                    <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
                </application-information>
                <submission-information>
                    <!-- submission-type "fdast1" is original-application -->
                    <submission-id submission-type="fdast1">0001</submission-id>
                    <!-- submission-sub-type "fdasst4" is amendment -->
                    <sequence-number submission-sub-type="fdasst4">0005</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
                    <form form-type="fdaft2">
                        <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0005.pdf" xlink:type="simple">
                            <title>Form FDA 356h - Response to IR dated 06-30-2011</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0005.pdf" xlink:type="simple">
```

```
                <title>Cover Letter - Response to IR dated 06-30-2011</title>
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #6: NDA Efficacy Supplement (new indication)


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
   <applicant-info>
      <id>123456789</id>
      <company-name>Good Drugs</company-name>
            <submission-description>Efficacy Supplement – PAS New Indication: Fever</submission-description>
             <applicant-contacts>
                <applicant-contact>
                    <!--applicant-contact-type "fdaact1" is regulatory -->
                    <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                    <telephones>
                        <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3 is mobile-telephone -->
                        <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                    </telephones>
                    <emails>
                        <email>jane.smith@gooddrugs.com</email>
                    </emails>
         </applicant-contact>
                <applicant-contact>
                    <!-- applicant-contact-type "fdaact2" is technical -->
                    <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                        <telephones>
                            <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                            <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                    </telephones>
                    <emails>
                        <email>john.smith@gooddrugs.com</email>
```

```
                    </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

        <application-set>
            <application application-containing-files="true">
                <application-information>
                    <!-- application-type "fdaat1" is NDA -->
                    <application-number application-type="fdaat1">456789</application-number>
                    <!-- application-type "fdaat5" is DMF -->
                    <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
                    <cross-reference-application-number application-type="fdaat5">765321</cross-reference-application-number>
                </application-information>
                <submission-information>
                    <!-- submission-type "fdast2" is efficacy-supplement; supplement-effective-date "fdasedt1" is PAS -->
                    <submission-id submission-type="fdast2" supplement-effective-date-type="fdasedt1">0006</submission-id>
                    <!-- submission-sub-type "fdasst3" is application -->
                    <sequence-number submission-sub-type="fdasst3">0006</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
                    <form form-type="fdaft2">
                        <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0006.pdf" xlink:type="simple">
                            <title>Form FDA 356h - Efficacy Supplement - Indication: fever</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0006.pdf" xlink:type="simple">
                <title>Cover Letter - Efficacy Supplement - Indication: fever</title>
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```

Example #7: NDA Annual Report


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Annual Report - 12-31-2009 through 12-30-2010</submission-description>
     <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3 is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                </telephones>
                <emails>
                    <email>jane.smith@gooddrugs.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                    <telephones>
                        <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
                    <email>john.smith@gooddrugs.com</email>
                </emails>
      </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
```

```
                <application-information>
                    <!-- application-type "fdaat1" is NDA -->
                    <application-number application-type="fdaat1">456789</application-number>
                    </application-information>
                <submission-information>
                    <!-- submission-type "fdast5" is annual-report -->
                    <submission-id submission-type="fdast5">0007</submission-id>
                    <!-- submission sub-type "fdasst6" is report -->
                    <sequence-number submission-sub-type="fdasst6">0007</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
            <form form-type="fdaft2">
                <leaf ID="a11383b1215534dfdf8a81df05237f691" checksum="49e154b9bee040a2de43c459affd92c9" checksum-type="md5" operation="new"
xlink:href="356h-nda456789-0007.pdf" xlink:type="simple">
                    <title>Form FDA 356h - 0007 - Annual Report 12-31-2009 through 12-30-2010</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-1-forms>
            <!-- form-type "fdaft4" is Form FDA 2252 -->
            <form form-type="fdaft4">
                <leaf ID="a11383b1215534dfdf8a81df05237f891" checksum="49e154b9bee040a2de43c459affd82c9" checksum-type="md5" operation="new"
xlink:href="2252-nda456789-0007.pdf" xlink:type="simple">
                    <title>Form FDA 2252 - 0007 - Annual Report 12-31-2009 through 12-30-2010</title>
                </leaf>
            </form>
        </m1-1-forms>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0007.pdf" xlink:type="simple">
                <title>Cover Letter - 0007 - Annual Report - 12-31-2009 through 12-30-2010</title>
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```

Example #8: Amendment #1 to an NDA Efficacy Supplement


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Amendment - Response to information request dated 7-01-2011</submission-description>
     <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                </telephones>
                <emails>
                    <email>jane.smith@gooddrugs.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                    <telephones>
                        <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
                    <email>john.smith@gooddrugs.com</email>
                </emails>
      </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
```

```
                <application-information>
                    <!-- application-type "fdaat1" is NDA -->
                    <application-number application-type="fdaat1">456789</application-number>
                    <!-- application-type "fdaat5" is DMF -->
                    <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
                </application-information>
                <submission-information>
                    <!-- submission-type "fdast2" is efficacy-supplement-->
                    <submission-id submission-type="fdast2">0006</submission-id>
                    <!-- submission-sub-type "fdasst4" is amendment-->
                    <sequence-number submission-sub-type="fdasst4">0008</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
                    <form form-type="fdaft2">
                        <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0008.pdf" xlink:type="simple">
                            <title>Form FDA 356h - 0008 - Amendment - Response</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0008.pdf" xlink:type="simple">
                <title>Cover Letter - 0008 - Amendment - Response</title>
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #9: NDA Labeling Supplement CBE-0


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
```

```
<applicant-info>
   <id>123456789</id>
   <company-name>Good Drugs</company-name>
         <submission-description>Labeling revisions to update adverse reactions</submission-description>
    <applicant-contacts>
               <applicant-contact>
                     <!--applicant-contact-type "fdaact1" is regulatory -->
                     <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                     <telephones>
                           <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                           <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                           <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                     </telephones>
                     <emails>
                           <email>jane.smith@gooddrugs.com</email>
                     </emails>
      </applicant-contact>
               <applicant-contact>
                     <!-- applicant-contact-type "fdaact2" is technical -->
                     <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                           <telephones>
                                 <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                                 <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                     </telephones>
                     <emails>
                           <email>john.smith@gooddrugs.com</email>
                     </emails>
      </applicant-contact>
   </applicant-contacts>
</applicant-info>

   <application-set>
         <application application-containing-files="true">
               <application-information>
                     <!-- application-type "fdaat1" is NDA -->
                     <application-number application-type="fdaat1">456789</application-number>
                     <!-- application-type "fdaat5" is DMF -->
                     <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
                     </application-information>
               <submission-information>
```

```
                <!-- submission-type "fdast4" is labeling supplement; supplement-effective-date "fdasedt2" is CBE-0 -->
                <submission-id submission-type="fdast4" supplement-effective-date-type="fdasedt2">0009</submission-id>
                <!-- submission-sub-type "fdasst3" is application -->
                <sequence-number submission-sub-type="fdasst3">0009</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0009.pdf" xlink:type="simple">
                        <title>Form FDA 356h - 0009 - Labeling Supplement - Labeling revisions to update adverse reactions</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0009.pdf" xlink:type="simple">
            <title>Cover Letter - 0009 - Labeling Supplement - Labeling revisions to update adverse reactions</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #10: Amendment #2 to an NDA Efficacy Supplement


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Additional safety information</submission-description>
    <applicant-contacts>
            <applicant-contact>
```

```
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3 is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
                </telephones>
                <emails>
                    <email>jane.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                    <telephones>
                        <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
                    <email>john.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
    </applicant-contacts>
</applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">456789</application-number>
                <!-- application-type "fdaat5" is DMF -->
                <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
                </application-information>
            <submission-information>
                <!-- submission-type "fdast2" is efficacy-supplement-->
                <submission-id submission-type="fdast2">0006</submission-id>
                <!-- submission-sub-type "fdasst4" is amendment -->
                <sequence-number submission-sub-type="fdasst4">0010</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
```

```
                    <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0010.pdf" xlink:type="simple">
                        <title>Form FDA 356h - 0010  Amendment - Additional safety information</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0010.pdf" xlink:type="simple">
            <title>Cover Letter - 0010 - Amendment - Additional safety information</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #11: Grouped NDA Labeling Supplement


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Grouped Labeling Supplement to 3 Applications - Addition of drug interaction information</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
```

```
                    </telephones>
                    <emails>
                        <email>jane.smith@gooddrugs.com</email>
                    </emails>
            </applicant-contact>
                <applicant-contact>
                    <!-- applicant-contact-type "fdaact2" is technical -->
                    <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                        <telephones>
                            <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                            <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                    </telephones>
                    <emails>
                        <email>john.smith@gooddrugs.com</email>
                    </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

        <application-set>
            <application application-containing-files="true">
                <application-information>
                    <!-- application-type "fdaat1" is NDA -->
                    <application-number application-type="fdaat1">456789</application-number>
                    <!-- application-type "fdaat5" is DMF -->
                    <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
                </application-information>
                <submission-information>
                    <!-- submission-type "fdast4" is labeling supplement; supplement-effective-date "fdasedt2" is CBE-0 -->
                    <submission-id submission-type="fdast4" supplement-effective-date-type="fdasedt2">0011</submission-id>
                    <!-- submission-sub-type "fdasst3" is application -->
                    <sequence-number submission-sub-type="fdasst3">0011</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
                    <form form-type="fdaft2">
                        <leaf ID="a11383c1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0011.pdf" xlink:type="simple">
                            <title>Form FDA 356h - NDA 456789 - Labeling Supplement - Addition of drug interaction information</title>
                        </leaf>
                    </form>
                </submission-information>
```

```
        </application>

        <application application-containing-files="false">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">567890</application-number>
                <!-- application-type "fdaat5" is DMF -->
                <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast4" is labeling supplement; supplement-effective-date "fdasedt2" is CBE-0 -->
                <submission-id submission-type="fdast4" supplement-effective-date-type="fdasedt2">0014</submission-id>
                <!-- submission-sub-type "fdasst3" is application -->
                <sequence-number submission-sub-type="fdasst3">0014</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383d1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63f4" checksum-type="md5"
operation="new" xlink:href="356h-nda567890-0014.pdf" xlink:type="simple">
                        <title>Form FDA 356h - NDA 567890 - Labeling Supplement - Addition of drug interaction information</title>
                    </leaf>
                </form>
            </submission-information>
        </application>

        <application application-containing-files="false">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">678901</application-number>
                <!-- application-type "fdaat5" is DMF -->
                <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast4" is labeling supplement; supplement-effective-date "fdasedt2" is CBE-0 -->
                <submission-id submission-type="fdast4" supplement-effective-date-type="fdasedt2">0012</submission-id>
                <!-- submission-sub-type "fdasst3" is application -->
                <sequence-number submission-sub-type="fdasst3">0012</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383e1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63g4" checksum-type="md5"
operation="new" xlink:href="356h-nda678901-0012.pdf" xlink:type="simple">
```

```
                <title>Form FDA 356h - NDA 678901 - Labeling Supplement - Addition of drug interaction information</title>
            </leaf>
        </form>
    </submission-information>
  </application>
 </application-set>
</admin>

<m1-regional>
 <m1-2-cover-letters>
  <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-grouped-labeling.pdf" xlink:type="simple">
    <title>Cover Letter - Grouped Labeling Supplement to 3 Applications - Addition of drug interaction information</title>
  </leaf>
 </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #12: Amendment to a Grouped NDA Labeling Supplement


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
      <submission-description>Amendment to grouped Labeling Supplement - Response to comments on draft labeling</submission-description>
    <applicant-contacts>
      <applicant-contact>
        <!--applicant-contact-type "fdaact1" is regulatory -->
        <applicant-contact-name applicant-contact-type="fdaact1">Jane Smith</applicant-contact-name>
        <telephones>
          <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3 is mobile-telephone -->
          <telephone telephone-number-type="fdatnt1">1-212-555-1234</telephone>
          <telephone telephone-number-type="fdatnt3">1-212-555-5678</telephone>
        </telephones>
```

```
                <emails>
                    <email>jane.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2 is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                    <telephones>
                        <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
                    <email>john.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">456789</application-number>
                <!-- application-type "fdaat5" is DMF -->
                <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast4" is labeling supplement -->
                <submission-id submission-type="fdast4">0011</submission-id>
                <!-- submission-sub-type "fdasst4" is amendment -->
                <sequence-number submission-sub-type="fdasst4">0012</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383c1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-nda456789-0012.pdf" xlink:type="simple">
                        <title>Form FDA 356h - NDA 456789 - Amendment to Labeling Supplement - Response to comments on draft labeling</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
```

```
<application application-containing-files="false">
    <application-information>
        <!-- application-type "fdaat1" is NDA -->
        <application-number application-type="fdaat1">567890</application-number>
        <!-- application-type "fdaat5" is DMF -->
        <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
    </application-information>
    <submission-information>
        <!-- submission-type "fdast4" is labeling supplement-->
        <submission-id submission-type="fdast4">0014</submission-id>
        <!-- submission-sub-type "fdasst4" is amendment -->
        <sequence-number submission-sub-type="fdasst4">0015</sequence-number>
        <!-- form-type "fdaft2" is Form FDA 356h -->
        <form form-type="fdaft2">
            <leaf ID="a11383d1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63f4" checksum-type="md5"
operation="new" xlink:href="356h-nda567890-0015.pdf" xlink:type="simple">
                <title>Form FDA 356h - NDA 567890 - Amendment to Labeling Supplement - Response to comments on draft labeling</title>
            </leaf>
        </form>
    </submission-information>
</application>

<application application-containing-files="false">
    <application-information>
        <!-- application-type "fdaat1" is NDA -->
        <application-number application-type="fdaat1">678901</application-number>
        <!-- application-type "fdaat5" is DMF -->
        <cross-reference-application-number application-type="fdaat5">012345</cross-reference-application-number>
    </application-information>
    <submission-information>
        <!-- submission-type "fdast4" is labeling supplement -->
        <submission-id submission-type="fdast4">0012</submission-id>
        <!-- submission-sub-type "fdasst4" is amendment -->
        <sequence-number submission-sub-type="fdasst4">0013</sequence-number>
        <!-- form-type "fdaft2" is Form FDA 356h -->
        <form form-type="fdaft2">
            <leaf ID="a11383e1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63g4" checksum-type="md5"
operation="new" xlink:href="356h-nda678901-0013.pdf" xlink:type="simple">
                <title>Form FDA 356h - NDA 678901 - Amendment to Labeling Supplement - Response to comments on draft labeling</title>
```

```
                    </leaf>
                </form>
            </submission-information>
        </application>

    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-amend-global-labeling.pdf" xlink:type="simple">
            <title>Cover Letter - Amendment to grouped Labeling Supplement - Response to comments on draft labeling</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #13: Promotional Labeling Advertising (Request for Advisory - Launch Materials)


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Request for advisory - Launch - Professional website, print ad, and sales aid</submission-description>
     <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact4" is Promotional Labeling and Advertising Regulatory Contact -->
                <applicant-contact-name applicant-contact-type="fdaact4">Larry Jones</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1235</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5679</telephone>
                </telephones>
```

```
                <emails>
                    <email>larry.jones@gooddrugs.com</email>
                </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                    <telephones>
                        <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
                    <email>john.smith@gooddrugs.com</email>
                </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">456789</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast8" is promotional-labeling-advertising -->
                <submission-id submission-type="fdast8">0013</submission-id>
                <!-- submission-sub-type "fdasst1" is original -->
                <sequence-number submission-sub-type="fdasst1">0013</sequence-number>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <!-- promotional-material-audience-type "fdapmat2" is professional -->
    <m1-15-promotional-material promotional-material-audience-type="fdapmat2">
        <m1-15-1-correspondence-relating-to-promotional-materials>
            <m1-15-1-1-request-for-advisory-comments-on-launch-materials>
```

```
                <leaf ID="a11383b1215534dfdf8a81df05237f700" checksum="49e154b9bee040a2de43c459affd6300" checksum-type="md5"
operation="new" xlink:href="correspondence-advisory-launch.pdf" xlink:type="simple">
                    <title>Request for professional launch advisory for website, print ad, and sales aid 20120115</title>
                </leaf>
            </m1-15-1-1-request-for-advisory-comments-on-launch-materials>
        </m1-15-1-correspondence-relating-to-promotional-materials>
        <!-- promotional-material-doc-type "fdapmdt2" is request-for-advisory-launch -->
        <m1-15-2-materials promotional-material-doc-type="fdapmdt2">
            <!-- promotional-material-type "fdapmt36" is website; the material-id is determined and provided by the applicant -->
            <m1-15-2-1-material promotional-material-type="fdapmt36" material-id="78GHSST">
                <m1-15-2-1-1-clean-version>
                    <leaf ID="a11383b1215534dfdf8a81df05237f704" checksum="49e154b9bee040a2de43c459affd6304" checksum-type="md5"
operation="new" xlink:href="clean-website.pdf" xlink:type="simple">
                        <title>WEBSITE 78GHSST Another treatment for 20120115 CLEAN</title>
                    </leaf>
                </m1-15-2-1-1-clean-version>
                <m1-15-2-1-2-annotated-version>
                    <leaf ID="a11383b1215534dfdf8a81df05237f705" checksum="49e154b9bee040a2de43c459affd6305" checksum-type="md5"
operation="new" xlink:href="annotated-website.pdf" xlink:type="simple">
                        <title>WEBSITE 78GHSST Another treatment for 20120115 ANNOTATED</title>
                    </leaf>
                </m1-15-2-1-2-annotated-version>
                <m1-15-2-1-3-annotated-labeling-version>
                    <leaf ID="a11383b1215534dfdf8a81df05237f706" checksum="49e154b9bee040a2de43c459affd6306" checksum-type="md5"
operation="new" xlink:href="annotated-label-website.pdf" xlink:type="simple">
                        <title>DRUG PI Annotated to Website</title>
                    </leaf>
                </m1-15-2-1-3-annotated-labeling-version>
                <m1-15-2-1-4-annotated-references>
                    <leaf ID="b21383b1215534ioif8a81df05237f784" checksum="49e154b9bee040a2de43c459hnvd6307" checksum-type="md5"
operation="new" xlink:href="annotated-ref1-website.pdf" xlink:type="simple">
                        <title>Reference 1 Smith et al for Website</title>
                    </leaf>
                    <leaf ID="b21383b1215534ioif8a81df05237f924" checksum="49e154b9bee040a2de43c459hnvd8947" checksum-type="md5"
operation="new" xlink:href="annotated-ref2-website.pdf" xlink:type="simple">
                        <title>Reference 2 Louis et al for Website</title>
                    </leaf>
                    <leaf ID="c31383b1215534ioif8a81df05237f784" checksum="49e154b9bee040a2de43c459hnvd6307" checksum-type="md5"
operation="new" xlink:href="annotated-ref3-website.pdf" xlink:type="simple">
                        <title>Reference 3 Goldstein et al for Website</title>
```

```
                    </leaf>
                </m1-15-2-1-4-annotated-references>
            </m1-15-2-1-material>

            <!-- promotional-material-type "fdapmt19" is print-ad; the material-id is determined and provided by the applicant -->
            <m1-15-2-1-material promotional-material-type="fdapmt19" material-id="56GJTSS">
                <m1-15-2-1-1-clean-version>
                    <leaf ID="a11383b1215534dfdf8a81df05237f701" checksum="49e154b9bee040a2de43c459affd6301" checksum-type="md5"
operation="new" xlink:href="clean-print-ad.pdf" xlink:type="simple">
                        <title>PRINT AD 56GJTSS Are you ready for a treatment 20120115 CLEAN</title>
                    </leaf>
                </m1-15-2-1-1-clean-version>
                <m1-15-2-1-2-annotated-version>
                    <leaf ID="a11383b1215534dfdf8a81df05237f702" checksum="49e154b9bee040a2de43c459affd6302" checksum-type="md5"
operation="new" xlink:href="annotated-print-ad.pdf" xlink:type="simple">
                        <title>PRINT AD 56GJTSS Are you ready for a treatment 20120115 ANNOTATED</title>
                    </leaf>
                </m1-15-2-1-2-annotated-version>
                <m1-15-2-1-3-annotated-labeling-version>
                    <leaf ID="a11383b1215534dfdf8a81df05237f703" checksum="49e154b9bee040a2de43c459affd6303" checksum-type="md5"
operation="new" xlink:href="annotated-label-print-ad.pdf" xlink:type="simple">
                        <title>DRUG PI Annotated to Print Ad</title>
                    </leaf>
                </m1-15-2-1-3-annotated-labeling-version>
                <m1-15-2-1-4-annotated-references>
                    <leaf ID="b21383b1215534dfdf8a81df05237f784" checksum="49e154b9bee040a2de43c459brwd6307" checksum-type="md5"
operation="new" xlink:href="annotated-ref1-print-ad.pdf" xlink:type="simple">
                        <title>Reference 1 American Academy of DA for Print Ad</title>
                    </leaf>
                    <leaf ID="b21383b1215534dfdf8a81df05237f924" checksum="49e154b9bee040a2de43c459brwd8947" checksum-type="md5"
operation="new" xlink:href="annotated-ref2-print-ad.pdf" xlink:type="simple">
                        <title>Reference 2 Holstein et al for Print Ad</title>
                    </leaf>
                </m1-15-2-1-4-annotated-references>
            </m1-15-2-1-material>

            <!-- promotional-material-type "fdapmt25" is sales-aid; the material-id is determined and provided by the applicant -->
            <m1-15-2-1-material promotional-material-type="fdapmt25" material-id="58FISSS">
                <m1-15-2-1-1-clean-version>
```

```
                <leaf ID="b21383b1215534dfdf8a81df05237f704" checksum="49e154b9bee040a2de43c459affd6304" checksum-type="md5"
operation="new" xlink:href="clean-sales-aid.pdf" xlink:type="simple">
                    <title>SALES AID 58FISSS Treating your patients 20120115 CLEAN</title>
                </leaf>
            </m1-15-2-1-1-clean-version>
            <m1-15-2-1-2-annotated-version>
                <leaf ID="b21383b1215534dfdf8a81df05237f705" checksum="49e154b9bee040a2de43c459affd6305" checksum-type="md5"
operation="new" xlink:href="annotated-sales-aid.pdf" xlink:type="simple">
                    <title>SALES AID 58FISSS Treating your patients 20120115 ANNOTATED</title>
                </leaf>
            </m1-15-2-1-2-annotated-version>
            <m1-15-2-1-3-annotated-labeling-version>
                <leaf ID="b21383b1215534dfdf8a81df05237f706" checksum="49e154b9bee040a2de43c459affd6306" checksum-type="md5"
operation="new" xlink:href="annotated-label-sales-aid.pdf" xlink:type="simple">
                    <title>DRUG PI Annotated to Sales Aid</title>
                </leaf>
            </m1-15-2-1-3-annotated-labeling-version>
            <m1-15-2-1-4-annotated-references>
                <leaf ID="a11383b1215534dfdf8a81df05237f924" checksum="49e154b9bee040a2de43c459brwd8947" checksum-type="md5"
operation="new" xlink:href="annotated-ref1-sales-aid.pdf" xlink:type="simple">
                    <title>Reference 1 Hastings et al for Sales Aid</title>
                </leaf>
            </m1-15-2-1-4-annotated-references>
        </m1-15-2-1-material>
    </m1-15-2-materials>
  </m1-15-promotional-material>
</m1-regional>
</fda-regional:fda-regional>
```


Example #14: Resubmission of a Promotional Labeling Advertising Submission


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
```

```
        <submission-description>Revised WEBSITE launch advisory correspondence 20120401 MA34</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact4" is Promotional Labeling and Advertising Regulatory Contact -->
                <applicant-contact-name applicant-contact-type="fdaact4">Larry Jones</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-1235</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-5679</telephone>
                </telephones>
                <emails>
                    <email>larry.jones@gooddrugs.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                    <telephones>
                        <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                </telephones>
                <emails>
                    <email>john.smith@gooddrugs.com</email>
                </emails>
      </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">456789</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast8" is promotional-labeling-advertising -->
                <submission-id submission-type="fdast8">0013</submission-id>
                <!-- submission-sub-type "fdasst5" is resubmission -->
                <sequence-number submission-sub-type="fdasst5">0014</sequence-number>
            </submission-information>
```

```
            </application>
        </application-set>
</admin>

<m1-regional>
        <!-- promotional-material-audience-type "fdapmat2" is professional -->
        <m1-15-promotional-material promotional-material-audience-type="fdapmat2">
        <m1-15-1-correspondence-relating-to-promotional-materials>
        <m1-15-1-1-request-for-advisory-comments-on-launch-materials>
                                <leaf ID="c31383b1215534dfdf8a81df05237f704" checksum="49e154b9bee040a2de43c459affd7404" checksum-type="md5"
operation="append" modified-file="../../../0013/m1/us/us-regional.xml#a11383b1215534dfdf8a81df05237f700" xlink:href="request-for-advisory-comments.pdf"
xlink:type="simple">
                                <title>Revised WEBSITE launch advisory correspondence 20120401 MA34</title>
                            </leaf>
            </m1-15-1-1-request-for-advisory-comments-on-launch-materials>
            </m1-15-1-correspondence-relating-to-promotional-materials>
            <!-- promotional-material-doc-type "fdpmdt2" is request for advisory launch -->
            <m1-15-2-materials promotional-material-doc-type="fdapmdt2">
                <!-- promotional-material-type "fdapmt36" is www-website; the material-id is determined and provided by the applicant -->
                <m1-15-2-1-material promotional-material-type="fdapmt36" material-id="78GHSST">
                    <m1-15-2-1-1-clean-version>
                        <leaf ID="b21383b1215534dfdf8a81df05237g314" checksum="49e154b9bee040a2de43c459affd6414" checksum-type="md5"
operation="replace" modified-file="../../../0013/m1/us/us-regional.xmla11383b1215534dfdf8a81df05237f704" xlink:href="website-clean.pdf"
xlink:type="simple">
                                <title>WEBSITE 78GHSST Another treatment for Pain 20120401 CLEAN</title>
                        </leaf>
                    </m1-15-2-1-1-clean-version>
                    <m1-15-2-1-2-annotated-version>
                                        <leaf ID="b21383b1215534dfdf8a81df05237g304" checksum="49e154b9bee040a2de43c459affd5424"
checksum-type="md5" operation="replace" modified-file="../../../0013/m1/us/us-regional.xml#a11383b1215534dfdf8a81df05237f705" xlink:href="annotated-
website-0014.pdf" xlink:type="simple">
                                <title>WEBSITE 78GHSST Another treatment for Pain 20120401 ANNOTATED</title>
                        </leaf>
                    </m1-15-2-1-2-annotated-version>
                    <m1-15-2-1-3-annotated-labeling-version>
                                            <leaf ID="b21383b1215534dfdf8a81df05237h304" checksum="49e154b9bee040a2de43c459affd4304"
checksum-type="md5" operation="replace" modified-file="../../../0013/m1/us/us-regional.xml#a11383b1215534dfdf8a81df05237f706" xlink:href="annotated-
label-website-0014.pdf" xlink:type="simple">
                                <title>DRUG PI ANNOTATED to Website</title>
                        </leaf>
```

```
                    </m1-15-2-1-3-annotated-labeling-version>
                    <m1-15-2-1-4-annotated-references>
                                        <leaf ID="b21383b1215534dfdf8a81df05237h305" checksum="49e154b9bee040a2de43c459affd3314"
checksum-type="md5" operation="replace" modified-file="../../../0013/m1/us/us-regional.xml#b21383b1215534ioif8a81df05237f784" xlink:href="annotated-
ref1-website-0014.pdf" xlink:type="simple">
                              <title>Reference 1 Smith et al. for Website</title>
                          </leaf>
                                        <leaf ID="b21383b1215534dfdf8a81df05237h306" checksum="49e154b9bee040a2de43c459affd2324"
checksum-type="md5" operation="replace" modified-file="../../../0013/m1/us/us-regional.xml#b21383b1215534ioif8a81df05237f924" xlink:href="annotated-
ref2-website-0014.pdf" xlink:type="simple">
                              <title>Reference 2 Louis et al. for Website</title>
                          </leaf>
                                        <leaf ID="b21383b1215534dfdf8a81df05237h307" checksum="49e154b9bee040a2de43c459hnvd6325"
checksum-type="md5" operation="replace" modified-file="../../../0013/m1/us/us-regional.xml#c31383b1215534ioif8a81df05237f754" xlink:href="annotated-
ref3-website-0014.pdf" xlink:type="simple">
                              <title>Reference 3 Goldstein et al for Website</title>
                          </leaf>
                    </m1-15-2-1-4-annotated-references>
                </m1-15-2-1-material>
            </m1-15-2-materials>
        </m1-15-promotional-material>
</m1-regional>
</fda-regional:fda-regional>
```


Example #15: Promotional - Withdrawal Request for Launch Advisory


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
   <applicant-info>
      <id>123456789</id>
      <company-name>Good Drugs</company-name>
            <submission-description>Withdrawal Request for Launch Advisory Print Ad MA34</submission-description>
       <applicant-contacts>
                <applicant-contact>
                    <!--applicant-contact-type "fdaact4" is Promotional Labeling and Advertising Regulatory Contact -->
                    <applicant-contact-name applicant-contact-type="fdaact4">Larry Jones</applicant-contact-name>
                    <telephones>
```

```
                <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                <telephone telephone-number-type="fdatnt1">1-212-555-1235</telephone>
                <telephone telephone-number-type="fdatnt3">1-212-555-5679</telephone>
            </telephones>
            <emails>
                <email>larry.jones@gooddrugs.com</email>
            </emails>
        </applicant-contact>
            <applicant-contact>
            <!-- applicant-contact-type "fdaact2" is technical -->
            <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
            </telephones>
            <emails>
                <email>john.smith@gooddrugs.com</email>
            </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
            <!-- application-type "fdaat1" is NDA -->
            <application-number application-type="fdaat1">456789</application-number>
            </application-information>
            <submission-information>
            <!-- submission-type "fdast8" is promotional-labeling-advertising -->
            <submission-id submission-type="fdast8">0013</submission-id>
            <!-- submission-sub-type "fdasst4" is amendment -->
            <sequence-number submission-sub-type="fdasst4">0015</sequence-number>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <!-- promotional-material-audience-type "fdapmat2" is professional -->
```

```
<m1-15-promotional-material promotional-material-audience-type="fdapmat2">
    <m1-15-1-correspondence-relating-to-promotional-materials>
    <m1-15-1-9-withdrawal-request>
                <leaf ID="a11383e1215892nfdf8a81em95237f796" checksum="49e154b9bee061v8de43c459affd13e4" checksum-type="md5"
operation="new" xlink:href="withdrawal-request-print-ad-ma34.pdf" xlink:type="simple">
            <title>Withdrawal request 20120405 for Print Ad MA34 submitted on 20120115</title>
        </leaf>
    </m1-15-1-9-withdrawal-request>
    </m1-15-1-correspondence-relating-to-promotional-materials>
        <!-- promotional-material-doc-type "fdpmdt2" is Request for Advisory Launch -->
    <m1-15-2-materials promotional-material-doc-type="fdapmdt2">
        <!-- promotional-material-type "fdapmt19" is Print Ad; the material-id is determined and provided by the applicant -->
        <m1-15-2-1-material promotional-material-type="fdapmt19" material-id="56GJTSS">
            <m1-15-2-1-1-clean-version>
                <leaf ID="b21383b1215534dfdf8a81df05237f704" checksum="" checksum-type="md5" operation="delete" modified-
file="../../../0013/m1/us/us-regional.xml#a11383b1215534dfdf8a81df05237f701" xlink:href="" xlink:type="simple">
                    <title>PRINT AD 56GJTSS Are you ready for a treatment 20120115 CLEAN</title>
                </leaf>
            </m1-15-2-1-1-clean-version>
            <m1-15-2-1-2-annotated-version>
                <leaf ID="b21593b1215534dfdf8a81df05237f704" checksum="" checksum-type="md5" operation="delete" modified-
file="../../../0013/m1/us/us-regional.xml#a11383b1215534dfdf8a81df05237f702"  xlink:href="" xlink:type="simple">
                    <title>PRINT AD 56GJTSS Are you ready for a treatment 20120115 ANNOTATED</title>
                </leaf>
            </m1-15-2-1-2-annotated-version>
            <m1-15-2-1-3-annotated-labeling-version>
                <leaf ID="a115943b1215534dfdf8a81df05237f703" checksum="" checksum-type="md5" operation="delete" modified-
file="../../../0013/m1/us/us-regional.xml#a11383b1215534dfdf8a81df05237f703" xlink:href="" xlink:type="simple">
                    <title>DRUG PI Annotated to Print Ad</title>
                </leaf>
            </m1-15-2-1-3-annotated-labeling-version>
            <m1-15-2-1-4-annotated-references>
                <leaf ID="b21595b1215534dfdf8a81df05237f784" checksum="" checksum-type="md5" operation="delete"  modified-
file="../../../0013/m1/us/us-regional.xml#b21383b1215534dfdf8a81df05237f784" xlink:href="" xlink:type="simple">
                    <title>Reference 1 American Academy of DA for Print Ad</title>
                </leaf>
                <leaf ID="b21596b1215534dfdf8a81df05237f924" checksum="" checksum-type="md5" operation="delete"  modified-
file="../../../0013/m1/us/us-regional.xml#b21383b1215534dfdf8a81df05237f924" xlink:href="" xlink:type="simple">
                    <title>Reference 2 Holstein et al for Print Ad</title>
                </leaf>
```

```
                    </m1-15-2-1-4-annotated-references>
                </m1-15-2-1-material>
            </m1-15-2-materials>
        </m1-15-promotional-material>
</m1-regional>
</fda-regional:fda-regional>
```


Example #16: Promotional Labeling-Advertising - 2253 submission


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
   <applicant-info>
      <id>123456789</id>
      <company-name>Good Drugs</company-name>
            <submission-description>Promotional Labeling-Advertising - 2253 submission - Professional sales aid</submission-description>
       <applicant-contacts>
                <applicant-contact>
                    <!--applicant-contact-type "fdaact4" is Promotional Labeling and Advertising Regulatory Contact -->
                    <applicant-contact-name applicant-contact-type="fdaact4">Larry Jones</applicant-contact-name>
                    <telephones>
                        <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                        <telephone telephone-number-type="fdatnt1">1-212-555-1235</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-5679</telephone>
                    </telephones>
                    <emails>
                        <email>larry.jones@gooddrugs.com</email>
                    </emails>
         </applicant-contact>
                <applicant-contact>
                    <!-- applicant-contact-type "fdaact2" is technical -->
                    <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                        <telephones>
                            <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                            <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                    </telephones>
                    <emails>
```

```
                <email>john.smith@gooddrugs.com</email>
            </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">456789</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast8" is promotional-labeling-advertising -->
                <submission-id submission-type="fdast8">0016</submission-id>
                <!-- submission-sub-type "fdasst1" is original -->
                <sequence-number submission-sub-type="fdasst1">0016</sequence-number>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-1-forms>
        <!-- form-type "fdaft5" is Form FDA 2253 -->
        <form form-type="fdaft5">
            <leaf ID="a11383b1215534dfdf8a81em95237f796" checksum="49e154b9bee094a2de43c459affd63e4" checksum-type="md5" operation="new"
xlink:href="2253-nda456789-0016.pdf" xlink:type="simple">
                <title>Form 2253 Professional sales aid 20120415</title>
            </leaf>
        </form>
    </m1-1-forms>
    <m1-14-labeling>
        <m1-14-6-product-labeling-for-2253-submissions>
            <leaf ID="a11383b1215892nfdf8a81em95237f796" checksum="49e154b9bee061v8de43c459affd63e4" checksum-type="md5" operation="new"
xlink:href="labeling-accompanying-material-0016.pdf" xlink:type="simple">
                <title>acetyl salicylic acid tablets PI Rev20120130</title>
            </leaf>
        </m1-14-6-product-labeling-for-2253-submissions>
    </m1-14-labeling>
```

```
    <!-- promotional-material-audience-type "fdapmat2" is professional -->
    <m1-15-promotional-material promotional-material-audience-type="fdapmat2">
        <!-- promotional-material-doc-type "fdpmdt1" is promotional-2253 -->
        <m1-15-2-materials promotional-material-doc-type="fdapmdt1">
            <!-- promotional-material-type "fdapmt25" is sales-aid; the material-id and issue date are determined and provided by the applicant -->
            <m1-15-2-1-material promotional-material-type="fdapmt25" material-id="65NO35482" issue-date="20120415">
                <m1-15-2-1-1-clean-version>
                    <leaf ID="b21383b1215534dfdf8a81df05237f704" checksum="49e154b9bee040a2de43c459affd6304" checksum-type="md5"
operation="new" xlink:href="clean-sales-aid.pdf" xlink:type="simple">
                        <title>SALES AID 65NO35482 Considerations for treatment 20120415</title>
                    </leaf>
                </m1-15-2-1-1-clean-version>
            </m1-15-2-1-material>
        </m1-15-2-materials>
    </m1-15-promotional-material>
</m1-regional>
</fda-regional:fda-regional>
```


Example #17: Grouped Promotional Submission (2253 Submission)


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456789</id>
    <company-name>Good Drugs</company-name>
        <submission-description>Grouped 2253 submission - Product Price Catalog</submission-description>
    <applicant-contacts>
        <applicant-contact>
            <!--applicant-contact-type "fdaact4" is Promotional Labeling and Advertising Regulatory Contact -->
            <applicant-contact-name applicant-contact-type="fdaact4">Larry Jones</applicant-contact-name>
            <telephones>
                <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                <telephone telephone-number-type="fdatnt1">1-212-555-1235</telephone>
                <telephone telephone-number-type="fdatnt3">1-212-555-5679</telephone>
            </telephones>
            <emails>
                <email>larry.jones@gooddrugs.com</email>
```

```
                    </emails>
            </applicant-contact>
                    <applicant-contact>
                        <!-- applicant-contact-type "fdaact2" is technical -->
                        <applicant-contact-name applicant-contact-type="fdaact2">John Smith</applicant-contact-name>
                            <telephones>
                                <telephone telephone-number-type="fdatnt1">1-212-555-1213</telephone>
                                <telephone telephone-number-type="fdatnt3">1-212-555-4546</telephone>
                        </telephones>
                        <emails>
                            <email>john.smith@gooddrugs.com</email>
                        </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

        <application-set>
                <application application-containing-files="true">
                    <application-information>
                        <!-- application-type "fdaat1" is NDA -->
                        <application-number application-type="fdaat1">456789</application-number>
                    </application-information>
                    <submission-information>
                        <!-- submission-type "fdast8" is promotional-labeling-advertising -->
                        <submission-id submission-type="fdast8">0017</submission-id>
                        <!-- submission-sub-type "fdasst1" is original -->
                        <sequence-number submission-sub-type="fdasst1">0017</sequence-number>
                    </submission-information>
                </application>

                <application application-containing-files="false">
                    <application-information>
                        <!-- application-type "fdaat1" is NDA -->
                        <application-number application-type="fdaat1">567890</application-number>
                    </application-information>
                    <submission-information>
                        <!-- submission-type "fdast8" is promotional-labeling-advertising -->
                        <submission-id submission-type="fdast8">0020</submission-id>
                        <!-- submission-sub-type "fdasst1" is original -->
                        <sequence-number submission-sub-type="fdasst1">0020</sequence-number>
```

```
            </submission-information>
        </application>

        <application application-containing-files="false">
            <application-information>
                <!-- application-type "fdaat1" is NDA -->
                <application-number application-type="fdaat1">678901</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast8" is promotional-labeling-advertising -->
                <submission-id submission-type="fdast8">0014</submission-id>
                <!-- submission-sub-type "fdasst1" is original -->
                <sequence-number submission-sub-type="fdasst1">0014</sequence-number>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-1-forms>
        <!-- form-type "fdaft5" is Form FDA 2253 -->
        <form form-type="fdaft5">
            <leaf ID="a11383b1215558nfdf8a81em95237f796" checksum="49e154b9bee094a2dm83c459affd63e4" checksum-type="md5"
operation="new" xlink:href="2253-20120430.pdf" xlink:type="simple">
                <title>Form 2253 Multiple Product Prof 20120430</title>
            </leaf>
<leaf ID="a11389b1215558nfdf8a81em95237f796" checksum="49e154b9bee094a2dm83c459affd63e4" checksum-type="md5" operation="new"
xlink:href="form-attachment.pdf" xlink:type="simple">
                <title>Form 2253 Attachment List of Additional Applications</title>
            </leaf>
        </form>
    </m1-1-forms>
    <m1-14-labeling>
        <m1-14-6-product-labeling-for-2253-submissions>
            <leaf ID="a11383x9845892nfdf8a81em95237f796" checksum="49e154b9nww061v8de43c459affd53e4" checksum-type="md5"
operation="new" xlink:href="labeling-accompanying-material.pdf" xlink:type="simple">
                <title>acetyl salicylic acid  PI Rev20120130</title>
            </leaf>
            <leaf ID="a11384x9845892nfdf8a81em95237f796" checksum="49e154b9nww061v8de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="labeling-accompanying-material-drug-x.pdf" xlink:type="simple">
```

```
                <title>Drug X PI Rev20120215</title>
            </leaf>
            <leaf ID="a11389x9845892nfdf8a81em95237f796" checksum="49e154b9nww061v8de43c459affd65e4" checksum-type="md5"
operation="new" xlink:href="labeling-accompanying-material-drug-z.pdf" xlink:type="simple">
                <title>Drug Z PI Rev20120228</title>
            </leaf>
        </m1-14-6-product-labeling-for-2253-submissions>
    </m1-14-labeling>
    <!-- promotional-material-audience-type "fdapmat2" is professional -->
    <m1-15-promotional-material promotional-material-audience-type="fdapmat2">
        <!-- promotional-material-doc-type "fdapmdt1" is promotional-2253 -->
        <m1-15-2-materials promotional-material-doc-type="fdapmdt1">
            <!-- promotional-material-type "fdapmt5" is catalog; the material-id and issue date are determined and provided by the applicant -->
            <m1-15-2-1-material promotional-material-type="fdapmt5" material-id="12PC35482" issue-date="20120430">
                <m1-15-2-1-1-clean-version>
                    <leaf ID="b21383b1861534dfdf8a81df05237f704" checksum="49e158f4bee040a2de43c459affd6304" checksum-type="md5"
operation="new" xlink:href="clean-catalog.pdf" xlink:type="simple">
                        <title>CATALOG 12PC35482 Product price catalog 20120430</title>
                    </leaf>
                </m1-15-2-1-1-clean-version>
            </m1-15-2-1-material>
        </m1-15-2-materials>
    </m1-15-promotional-material>
</m1-regional>
</fda-regional:fda-regional>
```


Example #18: Presubmission to a Rolling BLA


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456799</id>
    <company-name>Biologics Company</company-name>
        <submission-description>Rolling BLA – Part I - Module 3</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
```

```
                <applicant-contact-name applicant-contact-type="fdaact1">Cathy Jones</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3 is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-4321</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-8765</telephone>
                </telephones>
                <emails>
                    <email>cathy.jones@biologics-company.com</email>
                </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Roberts</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-3121</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6454</telephone>
                </telephones>
                <emails>
                    <email>john.roberts@biologics-company</email>
                </emails>
        </applicant-contact>
      </applicant-contacts>
    </applicant-info>

      <application-set>
          <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat3" is BLA -->
                <application-number application-type="fdaat3">654321</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast1" is original-application -->
                <submission-id submission-type="fdast1">0001</submission-id>
                <!-- submission-sub-type "fdasst2" is presubmission -->
                <sequence-number submission-sub-type="fdasst2">0001</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-0001.pdf" xlink:type="simple">
                        <title>Form FDA 356h 0001 Part I Rolling BLA - presubmission</title>
```

```
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0001.pdf" xlink:type="simple">
            <title>Cover Letter 0001 Part I Rolling BLA - presubmission</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #19: Presubmission to a Rolling BLA


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456799</id>
    <company-name>Biologics Company</company-name>
        <submission-description>Rolling BLA - Part II -  Module 4</submission-description>
   <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Cathy Jones</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-4321</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-8765</telephone>
                </telephones>
                <emails>
```

```
                <email>cathy.jones@biologics-company.com</email>
            </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Roberts</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-3121</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6454</telephone>
                </telephones>
                <emails>
                    <email>john.roberts@biologics-company.com</email>
                </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat3" is BLA -->
                <application-number application-type="fdaat3">654321</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast1" is original-application -->
                <submission-id submission-type="fdast1">0001</submission-id>
                <!-- submission-sub-type "fdasst2" is presubmission -->
                <sequence-number submission-sub-type="fdasst2">0002</sequence-number>
                <!-- form-type "fdaft2" is Form FDA 356h -->
                <form form-type="fdaft2">
                    <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-0002.pdf" xlink:type="simple">
                        <title>Form FDA 356h - 0002 Part 2 Rolling BLA - presubmissionn</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>
```

```
<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0002.pdf" xlink:type="simple">
            <title>Cover Letter - 0002 Part 2 Rolling BLA - presubmission</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #20: Original Application to a Rolling BLA


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456799</id>
    <company-name>Biologics Company</company-name>
        <submission-description>Rolling BLA – Original Application – Part III: Modules 1, 2, and 5</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Cathy Jones</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-4321</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-8765</telephone>
                </telephones>
                <emails>
                    <email>cathy.jones@biologics-company.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">John Roberts</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-3121</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6454</telephone>
```

```
                    </telephones>
                    <emails>
                        <email>john.roberts@biologics-company.com</email>
                    </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

        <application-set>
            <application application-containing-files="true">
                <application-information>
                    <!-- application-type "fdaat3" is BLA -->
                    <application-number application-type="fdaat3">654321</application-number>
                </application-information>
                <submission-information>
                    <!-- submission-type "fdast1" is original-application -->
                    <submission-id submission-type="fdast1">0001</submission-id>
                    <!-- submission-sub-type "fdasst3" is application -->
                    <sequence-number submission-sub-type="fdasst3">0003</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
                    <form form-type="fdaft2">
                        <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="bla654321-356h-0003.pdf" xlink:type="simple">
                            <title>Form FDA 356h 0003 Rolling BLA Original Application – Part III: Modules 1, 2, and 5</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0003.pdf" xlink:type="simple">
                <title>Cover Letter - Rolling BLA Original Application – Part III: Modules 1, 2, and 5</title>
            </leaf>
            <leaf ID="f88383b1215697dfdf8a81df05237f794" checksum="49e154b9iss284a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="reviewers-guide.pdf" xlink:type="simple">
                <title>Reviewers Guide for the Original Application</title>
```

```
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #21: Initial IND


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
   <applicant-info>
      <id>123456677</id>
      <company-name>Good Medicine Company</company-name>
            <submission-description>Initial IND 987654 indication: treatment for sneezing</submission-description>
      <applicant-contacts>
                  <applicant-contact>
                        <!--applicant-contact-type "fdaact1" is regulatory -->
                        <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                        <telephones>
                              <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3 is mobile-telephone -->
                              <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
                              <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
                        </telephones>
                        <emails>
                              <email>michael.smith@goodmedicine.com</email>
                        </emails>
         </applicant-contact>
                  <applicant-contact>
                        <!-- applicant-contact-type "fdaact2" is technical -->
                        <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
                        <telephones>
                              <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                              <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
                        </telephones>
                        <emails>
                              <email>mary.day@goodmedicine.com</email>
                        </emails>
```

```
        </applicant-contact>
      </applicant-contacts>
    </applicant-info>

      <application-set>
            <application application-containing-files="true">
                  <application-information>
                        <!-- application-type "fdaat4" is IND -->
                        <application-number application-type="fdaat4">987654</application-number>
                  </application-information>
                  <submission-information>
                        <!-- submission-type "fdast1" is original-application -->
                        <submission-id submission-type="fdast1">0001</submission-id>
                        <!-- submission-sub-type "fdasst3" is application -->
                        <sequence-number submission-sub-type="fdasst3">0001</sequence-number>
                        <!-- form-type "fdaft1" is Form FDA 1571 -->
                        <form form-type="fdaft1">
                              <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="1571-0001.pdf" xlink:type="simple">
                                    <title>Form FDA 1571 0001 Initial IND</title>
                              </leaf>
                        </form>
                  </submission-information>
            </application>
      </application-set>
</admin>

<m1-regional>
      <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0001.pdf" xlink:type="simple">
                  <title>Cover Letter - 0001 Initial IND</title>
            </leaf>
      </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```

Example #22: IND – IND Protocol Amendment


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456677</id>
    <company-name>Good Medicine Company</company-name>
        <submission-description>Protocol Amendment - New Protocol for Study 123</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
                </telephones>
                <emails>
                    <email>michael.smith@goodmedicine.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
                </telephones>
                <emails>
                    <email>mary.day@goodmedicine.com</email>
                </emails>
      </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
```

```
                <application-information>
                    <!-- application-type "fdaat4" is IND -->
                    <application-number application-type="fdaat4">987654</application-number>
                </application-information>
                <submission-information>
                    <!-- submission-type "fdast1" is original-application -->
                    <submission-id submission-type="fdast1">0001</submission-id>
                    <!-- submission-sub-type "fdasst4" is amendment-->
                    <sequence-number submission-sub-type="fdasst4">0002</sequence-number>
                    <!-- form-type "fdaft1" is Form FDA 1571 -->
                    <form form-type="fdaft1">
                        <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="1571-0002.pdf" xlink:type="simple">
                            <title>Form FDA 1571 0002 Protocol Amendment - New Protocol</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0002.pdf" xlink:type="simple">
                <title>Cover Letter 0002 Protocol Amendment - New Protocol</title>
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #23: IND – Initial Safety Report


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
   <applicant-info>
      <id>123456677</id>
```

```
    <company-name>Good Medicine Company</company-name>
        <submission-description>Initial Safety Report</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
                </telephones>
                <emails>
                    <email>michael.smith@goodmedicine.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
                </telephones>
                <emails>
                    <email>mary.day@goodmedicine.com</email>
                </emails>
      </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat4" is IND -->
                <application-number application-type="fdaat4">987654</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast9" is ind safety reports -->
                <submission-id submission-type="fdast9">0003</submission-id>
                <!-- submission-sub-type "fdasst6" is report -->
                <sequence-number submission-sub-type="fdasst6">0003</sequence-number>
```

```
                <!-- form-type "fdaft1" is Form FDA 1571 -->
                <form form-type="fdaft1">
                    <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="1571-0003.pdf" xlink:type="simple">
                        <title>Form FDA 1571 0003 Initial Safety Report</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0003.pdf" xlink:type="simple">
            <title>Cover Letter - 0003 Initial Safety Report</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #24: IND – Safety Report Follow-up #1


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456677</id>
    <company-name>Good Medicine Company</company-name>
        <submission-description>Follow-up 1 for Safety Report</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
```

```
                <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
            </telephones>
            <emails>
                <email>michael.smith@goodmedicine.com</email>
            </emails>
        </applicant-contact>
            <applicant-contact>
            <!-- applicant-contact-type "fdaact2" is technical -->
            <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
            <telephones>
                <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
            </telephones>
            <emails>
                <email>mary.day@goodmedicine.com</email>
            </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
            <!-- application-type "fdaat4" is IND -->
            <application-number application-type="fdaat4">987654</application-number>
            </application-information>
            <submission-information>
            <!-- submission-type "fdast9" is ind safety reports -->
            <submission-id submission-type="fdast9">0003</submission-id>
            <!-- submission-sub-type "fdasst4" is amendment -->
            <sequence-number submission-sub-type="fdasst4">0004</sequence-number>
            <!-- form-type "fdaft1" is Form FDA 1571 -->
            <form form-type="fdaft1">
                <leaf ID="a11383b1215534dfdf8a81df05237f796" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="1571-0004.pdf" xlink:type="simple">
                    <title>Form FDA 1571 0004 Follow-up Safety Report</title>
                </leaf>
            </form>
            </submission-information>
        </application>
```

```
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0004.pdf" xlink:type="simple">
            <title>Cover Letter - 0004 Follow-up Safety Report</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #25: Grouped Submission: DSUR to Multiple IND Applications


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456677</id>
    <company-name>Good Medicine Company</company-name>
        <submission-description>Development Safety Update Report (DSUR) Grouped submission to Multiple IND Applications</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
                </telephones>
                <emails>
                    <email>michael.smith@goodmedicine.com</email>
                </emails>
        </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
```

```
                <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
                </telephones>
                <emails>
                    <email>mary.day@goodmedicine.com</email>
                </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat4" is IND -->
                <application-number application-type="fdaat4">987654</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast5" is Annual Report -->
                <submission-id submission-type="fdast5">0005</submission-id>
                <!-- submission-sub-type "fdasst6" is report -->
                <sequence-number submission-sub-type="fdasst6">0005</sequence-number>
                <!-- form-type "fdaft1" is Form FDA 1571 -->
                <form form-type="fdaft1">
                    <leaf ID="a11383b1215534dfdf8a81df05237f785" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="1571-0005.pdf" xlink:type="simple">
                        <title>Form FDA 1571 IND-987654 0005 DSUR</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
        <application application-containing-files="false">
            <application-information>
                <!-- application-type "fdaat4" is IND -->
                <application-number application-type="fdaat4">999888</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast5" is Annual Report -->
                <submission-id submission-type="fdast5">0010</submission-id>
```

```
                <!-- submission-sub-type "fdasst6" is report -->
                <sequence-number submission-sub-type="fdasst6">0010</sequence-number>
                <!-- form-type "fdaft1" is Form FDA 1571 -->
                <form form-type="fdaft1">
                    <leaf ID="a11383b1215534dfdf8a81df05237f786" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="1571-0010.pdf" xlink:type="simple">
                        <title>Form FDA 1571 IND-999888 0010 DSUR</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
        <application application-containing-files="false">
            <application-information>
                <!-- application-type "fdaat4" is IND -->
                <application-number application-type="fdaat4">999777</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast5" is Annual Report -->
                <submission-id submission-type="fdast5">0015</submission-id>
                <!-- submission-sub-type "fdasst6" is report -->
                <sequence-number submission-sub-type="fdasst6">0015</sequence-number>
                <!-- form-type "fdaft1" is Form FDA 1571 -->
                <form form-type="fdaft1">
                    <leaf ID="a11383b1215534dfdf8a81df05237f787" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="1571-0015.pdf" xlink:type="simple">
                        <title>Form FDA 1571 IND-999777 0015 DSUR</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f789" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-dsur-2011.pdf" xlink:type="simple">
            <title>Cover Letter DSUR for 2011 to 3 INDs</title>
        </leaf>
    </m1-2-cover-letters>
```

```
<m1-13-annual-report>
    <m1-13-15-development-safety-update-report-dsur>
        <leaf ID="a11383b1215534dfdf8a81df05237f589" checksum="49e154b9bee040a2de43c459affd63e6" checksum-type="md5" operation="new"
xlink:href="dsur-2012.pdf" xlink:type="simple">
            <title>DSUR 2010-01-01 to 2011-12-31</title>
        </leaf>
</m1-13-15-development-safety-update-report-dsur>
</m1-13-annual-report>
</m1-regional>
</fda-regional:fda-regional>
```


Example #26: IND Meeting Request


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456677</id>
    <company-name>Good Medicine Company</company-name>
        <submission-description>Type A Meeting Request - SPA</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
                </telephones>
                <emails>
                    <email>michael.smith@goodmedicine.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
                <telephones>
```

```
                <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
            </telephones>
            <emails>
                <email>mary.day@goodmedicine.com</email>
            </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <application-set>
        <application application-containing-files="true">
            <application-information>
                <!-- application-type "fdaat4" is IND -->
                <application-number application-type="fdaat4">987654</application-number>
            </application-information>
            <submission-information>
                <!-- submission-type "fdast6" is product correspondence -->
                <submission-id submission-type="fdast6">0007</submission-id>
                <!-- submission-sub-type "fdasst7" is correspondence -->
                <sequence-number submission-sub-type="fdasst7">0007</sequence-number>
                <!-- form-type "fdaft1" is Form FDA 1571 -->
                <form form-type="fdaft1">
                    <leaf ID="a11383b1215534dfdf8a81df05237f496" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="1571-0007.pdf" xlink:type="simple">
                        <title>Form FDA 1571 0007 Type A Meeting Request - SPA</title>
                    </leaf>
                </form>
            </submission-information>
        </application>
    </application-set>
</admin>

<m1-regional>
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0007.pdf" xlink:type="simple">
            <title>Cover Letter - 0007 Type A Meeting Request - SPA</title>
        </leaf>
    </m1-2-cover-letters>
```

```
    <m1-6-meetings>
        <m1-6-1-meeting-request>
            <leaf ID="a11383b1215534dfdf8a81df05237f394" checksum="49e154b9bee040a2de43c459affd63e5" checksum-type="md5" operation="new"
xlink:href="meeting-request-spa-0007.pdf" xlink:type="simple">
                <title>Type A Meeting Request - SPA</title>
            </leaf>
        </m1-6-1-meeting-request>
    </m1-6-meetings>
</m1-regional>
</fda-regional:fda-regional>
```


Example #27: Amendment to 2 Efficacy supplements in the same application


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456677</id>
    <company-name>Good Medicine Company</company-name>
        <submission-description>Amendment to Two Efficacy Supplements (Migraine and Pain)</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
                </telephones>
                <emails>
                    <email>michael.smith@goodmedicine.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
                <telephones>
```

```
                <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
            </telephones>
            <emails>
                <email>mary.day@goodmedicine.com</email>
            </emails>
        </applicant-contact>
    </applicant-contacts>
  </applicant-info>

    <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="a11383b1215534dfdf8a81df05237f608" 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>
</admin>

<m1-regional>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0020.pdf" xlink:type="simple">
                <title>Cover Letter - 0020 Amendment to Two Efficacy Supplements</title>
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```

Examples - Transitioning from DTD Version 2.01 to DTD Version 3.3

The following examples show how the submission numbering would be handled when transitioning a legacy or existing application from the old DTD version 2.01 to the new DTD version 3.3.

The numbered examples in this section are designated with an “a” or “b” following the example number. The distinction of the “a” or “b” is defined below:

- “a” indicates that the xml code is from the Admin section according to the old DTD version 2.01
- “b” indicates that the xml code is from the Admin section according to the new DTD version 3.3

Example #28a: Legacy - Last amendment submitted using the old DTD Version 2.01

```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "../../util/dtd/us-regional-v2-01.dtd">
<?xml-stylesheet type="text/xsl" href="../../util/style/us-regional.xsl"?>
<fda-regional:fda-regional xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink" dtd-version="2.01">
        <admin>
                <applicant-info>
                        <company-name> Good Medicine Company </company-name>
                        <date-of-submission>
                                <date format="yyyymmdd">20111231</date>
                        </date-of-submission>
                </applicant-info>
                <product-description>
                        <application-number>987654</application-number>
<prod-name type="established">Good Medicine</prod-name></product-description>
    <application-information application-type="nda">
      <submission submission-type="amendment">
        <sequence-number>0014</sequence-number>
       <related-sequence-number>0000</related-sequence-number>
      </submission>
    </application-information>
  </admin>

<m1-regional>
    <m1-1-forms>
        <m1-1-2-fda-form-356h>
                        <leaf ID="ID49f2f29da255eb223b467a1f6bfc4710" checksum="2f916257589de87238285540bf03783d" checksum-type="md5"
operation="new" xlink:href="356h.pdf" xlink:type="simple">
```

```
                <title>FDA Form 356h 0014</title>
                </leaf>
            </m1-1-2-fda-form-356h>
    </m1-1-forms>
      <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0014.pdf" xlink:type="simple">
                <title>Cover Letter - 0014 Amendment</title>
            </leaf>
      </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #28b: 120-day Safety Update to a legacy application using the new DTD Version 3.3:

This 120-day safety update is being submitted as an amendment to an original application which is being transitioned from DTD version 2.01 to DTD version 3.3.


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
   <applicant-info>
      <id>123456677</id>
      <company-name>Good Medicine Company</company-name>
            <submission-description>120-Day Safety Update</submission-description>
      <applicant-contacts>
                <applicant-contact>
                    <!--applicant-contact-type "fdaact1" is regulatory -->
                    <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                    <telephones>
                        <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                        <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
                    </telephones>
                    <emails>
                        <email>michael.smith@goodmedicine.com</email>
                    </emails>
         </applicant-contact>
```

```
                <applicant-contact>
                    <!-- applicant-contact-type "fdaact2" is technical -->
                    <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
                    <telephones>
                        <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                        <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
                    </telephones>
                    <emails>
                        <email>mary.day@goodmedicine.com</email>
                    </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

        <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 "fdast1" is Original Application -->
                    <submission-id submission-type="fdast1">0000</submission-id>
                    <!-- submission-sub-type "fdasst4" is amendment -->
                    <sequence-number submission-sub-type="fdasst4">0015</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
                    <form form-type="fdaft2">
                        <leaf ID="a11383b1215534dfdf8a81df05237f601" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-0015.pdf" xlink:type="simple">
                            <title>Form FDA 356h 0015 120-day Safety Update</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-2-cover-letters>
```

```
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0015.pdf" xlink:type="simple">
                <title>Cover Letter - 0015 120-day Safety Update</title>
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #29a: Legacy - Original-application submitted using the old DTD Version 2.01:


```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "../../util/dtd/us-regional-v2-01.dtd">
<?xml-stylesheet type="text/xsl" href="../../util/style/us-regional.xsl"?>
<fda-regional:fda-regional xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink" dtd-version="2.01">
        <admin>
            <applicant-info>
                <company-name> Good Medicine Company </company-name>
                <date-of-submission>
                    <date format="yyyymmdd">20111001</date>
                </date-of-submission>
            </applicant-info>
            <product-description>
                <application-number>876543</application-number>
<prod-name type="proprietary">Cure It</prod-name></product-description>
    <application-information application-type="nda">
      <submission submission-type="original-application">
        <sequence-number>0002</sequence-number>
      </submission>
    </application-information>
  </admin>

<m1-regional>
    <m1-1-forms>
        <m1-1-2-fda-form-356h>
                <leaf ID="ID49f2f29da255eb223b467a1f6bfc4710" checksum="2f916257589de87238285540bf03783d" checksum-type="md5"
operation="new" xlink:href="356h.pdf" xlink:type="simple">
                <title>FDA Form 356h 0002 Original Application</title>
                </leaf>
            </m1-1-2-fda-form-356h>
      </m1-1-forms>
```

```
    <m1-2-cover-letters>
        <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0002.pdf" xlink:type="simple">
            <title>Cover Letter - 0002 Original Application</title>
        </leaf>
    </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```


Example #29b: Amendment to a legacy application using the new DTD Version 3.3:


```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "http://www.accessdata.fda.gov/static/eCTD/us-regional-v3-3.dtd">
<?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/static/eCTD/us-regional.xsl"?>
<fda-regional:fda-regional dtd-version="3.3" xml:lang="text" xmlns:fda-regional="http://www.ich.org/fda" xmlns:xlink="http://www.w3c.org/1999/xlink">
<admin>
  <applicant-info>
    <id>123456677</id>
    <company-name>Good Medicine Company</company-name>
        <submission-description>Amendment- Response to Safety Queries</submission-description>
    <applicant-contacts>
            <applicant-contact>
                <!--applicant-contact-type "fdaact1" is regulatory -->
                <applicant-contact-name applicant-contact-type="fdaact1">Michael Smith</applicant-contact-name>
                <telephones>
                    <!-- telephone-number-type "fdatnt1" is business-telephone; "fdatnt3" is mobile-telephone -->
                    <telephone telephone-number-type="fdatnt1">1-212-555-9876</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-6789</telephone>
                </telephones>
                <emails>
                    <email>michael.smith@goodmedicine.com</email>
                </emails>
      </applicant-contact>
            <applicant-contact>
                <!-- applicant-contact-type "fdaact2" is technical -->
                <applicant-contact-name applicant-contact-type="fdaact2">Mary Day</applicant-contact-name>
                <telephones>
                    <telephone telephone-number-type="fdatnt1">1-212-555-0123</telephone>
                    <telephone telephone-number-type="fdatnt3">1-212-555-3210</telephone>
                </telephones>
```

```
                <emails>
                    <email>mary.day@goodmedicine.com</email>
                </emails>
            </applicant-contact>
        </applicant-contacts>
    </applicant-info>

        <application-set>
            <application application-containing-files="true">
                <application-information>
                    <!-- application-type "fdaat4" is NDA -->
                    <application-number application-type="fdaat4">876543</application-number>
                </application-information>
                <submission-information>
                    <!-- submission-type "fdast1" is Original Application -->
                    <submission-id submission-type="fdast1">0002</submission-id>
                    <!-- submission-sub-type "fdasst4" is amendment -->
                    <sequence-number submission-sub-type="fdasst4">0003</sequence-number>
                    <!-- form-type "fdaft2" is Form FDA 356h -->
                    <form form-type="fdaft2">
                        <leaf ID="a11383b1215534dfdf8a81df05237f601" checksum="49e154b9bee040a2de43c459affd63e4" checksum-type="md5"
operation="new" xlink:href="356h-0003.pdf" xlink:type="simple">
                            <title>Form FDA 356h 0003 Amendment- Response to Safety Queries</title>
                        </leaf>
                    </form>
                </submission-information>
            </application>
        </application-set>
</admin>

<m1-regional>
        <m1-2-cover-letters>
            <leaf ID="a11383b1215534dfdf8a81df05237f794" checksum="49e154b9bee040a2de43c459affd63e3" checksum-type="md5" operation="new"
xlink:href="cover-0003.pdf" xlink:type="simple">
                <title>Cover Letter – 0003 Amendment- Response to Safety Queries</title>
            </leaf>
        </m1-2-cover-letters>
</m1-regional>
</fda-regional:fda-regional>
```