The eCTD BACKBONE FILES SPECIFICATION FOR MODULE 1

Revision History

Date	Version	Summary of Changes
2003-08-13	1.0	Original version
2004-03-01	1.1	Clarifications to the original version
2006-04-13	1.2	Change to Related Sequence Example
2006-12-13	1.3	Change to XML coding for a supplement to an original application related sequence example

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The eCTD Backbone Files Specification for Module 1 (Module 1 eCTD Backbone File)

This document provides specifications for creating the electronic common technical document (eCTD) backbone file for Modules 1 for use with the guidance to industry: *Providing Regulatory Submissions in Electronic Format — Human Pharmaceutical Applications and Related Submissions.*

The Module 1 eCTD Backbone File includes information for each file submitted in Module 1. The file information is provided within an XML element called the *leaf* element. The *leaf* elements are organized using the Module1 headings. The Module 1 headings are named and organized according to the subject matter of the information contained in the file. The heading information is provided as an XML element called *header* in this specification. In addition, the Module 1 eCTD Backbone File includes administrative information about each submission. The administrative information is provided in the *admin* element.

Because the Module 1 eCTD Backbone File may be used in a wide range of applications and related submission types, a specific submission may not use all of the possible *headings* elements. You should include the *header* needed to organize the files in your submission.

I. START OF THE MODULE 1 ECTD BACKBONE FILE

You should name the module 1eCTD Backbone File *us-regional.xml* and place it in the *us* folder that is in the folder named *m1* as described in *Providing Regulatory Submissions in Electronic Format — Human Pharmaceutical Applications and Related Submissions*. For example, the path for the us-regional.xml file for sequence number 0006 is 0006/m1/us/us-regional.xml. You should place a *leaf* element in the Module 2 to 5 eCTD Backbone File for the *us-regional.xml* file. In the corresponding Module 2 to 5 eCTD Backbone File, the *operation* attribute should have a value of “new”.

The header of the Module 1 eCTD Backbone File is always the same. It contains machine-readable information about the following:

- Version of XML being used
- Type of characters that are allowed in the file
- Location of the standards that control the organization of the file

A sample of the common elements is provided:

```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE fda-regional:fda-regional SYSTEM "../../util/us-regional.dtd">
        < fda-regional:fda-regional
                xmlns:ectd="http://www.ich.org/ectd"
                xmlns:xlink="hyyp://www.w3c.org/1999/xlink">
```

```
            <!--All the heading elements and content for module 1 should be
            provided after these elements and before the last element closing
            tag named </fda-regional:fda-regional> -->
        </fda-regional:fda-regional>
```

The elements used to organize files for Module1 are placed within the area represented by the comment in the example shown above. Information about creating those elements is provided in other sections of this specification.

II. ADMIN ELEMENTS

Administrative information is contained in the admin element which is contained in the *fda-regional:fda-regional* element[1]. There are three elements contained in the element named *admin:*. *applicant-info, product-description,* and *application-information*. These elements should be placed in the order as they are listed above.

```
<fda-regional:fda-regional>
    <admin>
        <applicant-info>
        </applicant-info>
        <product-description>
        </product-description>
        <applicant-information>
        </applicant-information>
    </admin>
</fda-regional:fda-regional>
```

. Applicant-info Element

The *application-info* elements contains the *applicant-info* element: *company-name*, and *date-of-submission*.

0. Company-name Element

The sponsor or applicant's name is in the *company-name* element. An example of the *company-name* element for the "VeryBest Drug Company" with its content is provided:

```
<company-name>VeryBest Drug Company</company-name>
```

You should provide this element with every submission.

0. Date-of-submission Element

[1] Both the start tag and the end tag of the admin element should be placed between the start and end tags of the:*fda-regional* element.

An element named *date* is contained in the *date-of-submission* element. You should place the date of submission in the *date* element. This is sometimes referred to as the "letter date" because it can be the same as the date on the cover letter. Provide an attribute for the *date* element named *format*. The format has a fixed value of "yyyymmdd" and indicates the content of the date element is the four-digit year followed by two-digit month followed by two-digit day.

An example of the *date-of-submission* element with its content is provided:

```
<date-of-submission>
        <date format="yyyymmdd">20020208</date>
</date-of-submission >
```

You should provide this element with every submission.

- **Product-description Element**

There are two elements contained in the *product-description* element: *application-number,* and *prod-name*.

0. Application-number Element

The 6 digit application number in placed in the *application-number* element. You should provide only the digits, including any leading zeros for the application number without letters or dashes. An example of the *application-number* element for NDA 99-999 with its content is provided:

```
<application-number>099999</application-number >
```

You should provide this element with every sequence number submission to the application.

0. Prod-name Element

The *prod-name* elements contains up to four different types of product name, all of which can occur in a single submission. Provide an attribute for the *prod-name* element named *type*. Indicate the *type* of product name you contained in the *prod-name* element by choosing one of the four allowed values. The table below lists the available product name types (*type* attribute values) with their meaning:

type Attribute and Value	Product Name Type
type="established"	Established name (e.g., proper name)
type="proprietary"	Proprietary name (e.g., brand name, trade name)
type="chemical"	Chemical name. (spell Greek characters and don't use superscript or subscript)
type="code"	Internal code used by the application sponsor.

There is no limit to the number of *prod-name* elements. An example of *prod-name* elements with their *type* attribute values and content is provided:

```
<prod-name type="proprietary">Cure All</prod-name >
<prod-name type="established">Cures</prod-name >
<prod-name type="chemical">H2O</prod-name >
<prod-name type="code">alpha-8</prod-name >
<prod-name type="code">beta-3</prod-name >
```

You should provide at least one *prod-name* element with each sequence numbered submission to the application.

. **Application-information Element**

The element *application-information* contains the *submission* element. You should provide an attribute for the *application-information* element named *application-type*. Indicate the type of application for this submission in the *application-type* element by choosing one of the types allowed. The table below lists the available application types (*application-type* attribute values) with their meaning:

application-type Attribute and Value	Application Type
application-type="nda"	New Drug Application
application-type="anda"	Abbreviated New Drug Application
application-type="bla"	Biologics License Application
application-type="ind"	Investigational new drug application.
application-type="dmf"	Master file

0. Submission Element

There are two elements in the *submission* element: *sequence-number*, and *related-sequence-number*. You should provide a *submission-type* attribute for the *submission* element that contains the value for the type of submission from the following table:

Submission-type Attribute Value	Meaning
“original-application"	A complete new application that has never before been submitted
"amendment"	All submissions to pending original submission or pending supplements to approved applications including responses to information request letters
"resubmission"	A complete response to an action letter, or submission of an application that has been the subject of a withdrawal or a refusal to file
"presubmission"	Information submitted prior to the submission of a complete new application
"annual-report"	Annual Reports to applications

Submission-type Attribute Value	Meaning
"establishment-description-supplement"	Supplements to the information contained in the establishment description section for biological products
"efficacy-supplement"	Submissions for such changes as a new indication or dosage regimen for an approved product, a comparative efficacy claim naming another product, or a significant alteration in the patient population; e.g., prescription to Over-The-Counter switch
"labeling-supplement"	All label change supplements required under 21 CFR 314.70 and 21 CFR 601.12 that do not qualify as efficacy supplements;
"chemistry-manufacturing-controls-supplement"	Manufacturing and Controls Supplement manufacturing change supplement submissions as provided in 21 CFR 314.70, 21 CFR 314.71, 21 CFR 314.72 and 21 CFR 601.12
"other"	Not among those listed above

) Sequence-number Element

You should include the sequence number of the submission in the *sequence-number* element. The sequence number should be exactly 4 digits with no spaces between them. You should provide a *sequence-number* element with every submission. Note that sequence numbers are used to differentiate between submissions for the same application and do not necessarily correspond to the order they are received by the Agency. An example of the first application sequence number element with its content is provided:

<sequence-number>0000</sequence-number>

) Related-sequence-number Element

When providing an amendment to an earlier submission, you should include the sequence number of the earlier submission in the *related-sequence-number* element. The sequence number should be exactly 4 digits with no spaces between them. If this submission is related to more than one previous submission, you should provide each previous submission's sequence number in a separate *related-sequence-number* element. There is no limit to the number of *related-sequence-number* elements. The following is an example of the related sequence number. An application has the following submissions:

0000 - Original application
0001 - an amendment to original application
0002 - an amendment to original application
0003 - a chemistry, manufacturing and control supplement
0004 - an amendment to original application
0005 - an amendment to the supplement
0006 - an amendment to the original application
0007 - an amendment that relates to both the original and supplement

A non-XML representation would relate this as:

Sequence-number	Related-sequence-number***
0000	
0001	0000
0002	0000
0003	
0004	0000
0005	0003
0006	0000
0007	0000 0003

Example XML coding for the original application would look like:

```
<submission submission-type="original-application">
        <sequence-number>0000</sequence-number>
</submission>
```

Example XML coding for a supplement to an original application would look like:

```
<submission submission-type="chemistry-manufacturing-controls-supplement ">
<sequence-number>0003</sequence-number>
</submission>
```

Example XML coding for a *submission* element of an amendment that would apply to two or more original submissions, such as sequence number 0007 above, would look like:

```
<submission submission-type="chemistry-manufacturing-controls-supplement">
        <sequence-number>0007</sequence-number>
        <related-sequence-number>0000</related-sequence-number>
        <related-sequence-number>0003</related-sequence-number>
</submission>
```

Example XML coding for an amendment to an original application or original supplement (example shown is for an amendment to the original application):

```
<submission submission-type="amendment">
    <sequence-number>0002</sequence-number>
    <related-sequence-number>0000</related-sequence-number>
</submission>
```

III. LEAF ELEMENT

Information for an individual document is contained in the leaf element, its attributes and its "title" element. The leaf element is used repeatedly throughout the eCTD backbone files to provide individual information for each document being submitted. Detailed descriptions of each part of the leaf element and how to use them are found in the document *The eCTD*

Backbone Files Specifications for Modules 2 through 5. When preparing the us-regional.xml file, the *xlink:href* and *modified-file leaf* attributes should reflect the path relative to the location of the us-regional.xml file location in the submission. The following is an example of a *xlink:href* attribute and its value for the 356h.pdf in module 1 in the same submission:

xlink:href="356h.pdf "

The following is a example of a *modified-file* leaf attribute and its value in module 1 in an earlier submission:

modified-file="../../../0001/m1/us/us-regional.xml#id34567

IV. HEADING ELEMENTS FOR MODULE 1

This is the equivalent to the *heading* elements described in the document The eCTD Backbone Files Specifications for Modules 2 through 5. This section describes the heading elements relevant to module 1.

The module 1 *heading* elements are listed in the following table. Both the start tag and end tag for each *heading* element are provided. If there are one or more subheadings for the heading, the corresponding element end tag will occur on the table row below the last relevant subheading. The *leaf* element is included to show where the leaf elements should be placed. The details for the *leaf* elements are not shown on this table to keep it clearer. The *leaf* elements should only occur where indicated in this table. A *heading* element may contain any number of *leaf* elements. If no documents are submitted for a heading, you should omit the element for that heading in the eCTD backbone file.

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
Regional information	<m1-regional>
0. Forms Choose one of the following elements to contain your form's leaf element.	<m1-1-forms>
) Investigational New Drug (IND)	<m1-1-1-fda-form-1571> <leaf> </leaf> </m1-1-1-fda-form-1571>
) New Drug Application (NDA) or New Biologic Application (BLA)	<m1-1-2-fda-form-356h> <leaf> </leaf> </m1-1-2-fda-form-356h>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) User Fee Cover Sheet	<m1-1-3-fda-form-3397> <leaf> </leaf> </m1-1-3-fda-form-3397>
) Annual Report Transmittal	<m1-1-4-fda-form-2252> <leaf> </leaf> </m1-1-4-fda-form-2252>
) Advertising and Promotional Labeling	<m1-1-5-fda-form-2253> <leaf> </leaf> </m1-1-5-fda-form-2253>
) Transmittal of Labels and Circulars	<m1-1-6-fda-form-2567> <leaf </leaf> </m1-1-6-fda-form-2567>
End of Forms	</m1-1-forms>
0. Cover Letters	<m1-2-cover-letters> <leaf> </leaf> </m1-2-cover-letters>
0. Administrative Information	<m1-3-administrative-information>
) Applicant Information	<m1-3-1-applicant-information>
(0) Change of Address	<m1-3-1-1-cofa-con> <leaf> </leaf> </m1-3-1-1-cofa-con>
(0) Change of Agent	<m1-3-1-2-change-contact-agent> <leaf> </leaf> </m1-3-1-2-change-contact-agent>
(0) Sponsor Change	<m1-3-1-3-change-sponsor> <leaf> </leaf> </m1-3-1-3-change-sponsor>
(0) Obligation Transfer	<m1-3-1-4-transfer-obligation> <leaf> </leaf> </m1-3-1-4-transfer-obligation>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
(0) Ownership Change	<m1-3-1-5-change-application-ownership> <leaf> </leaf> </m1-3-1-5-change-application-ownership>
End Applicant Information	</m1-3-1-applicant-information>
) Field Copy Certification	<m1-3-2-field-copy-certification> <leaf> </leaf> </m1-3-2-field-copy-certification>
) Debarment Certification	<m1-3-3-debarment-certification> <leaf> </leaf> </m1-3-3-debarment-certification>
) Financial Disclosure	<m1-3-4-financial-certification-disclosure> <leaf> </leaf> </m1-3-4-financial-certification-disclosure>
) Patent Exclusivity	<m1-3-5-patent-exclusivity>
(0) Patent Information	<m1-3-5-1-patent-information> <leaf> </leaf> </m1-3-5-1-patent-information>
(0) Patent Certification	<m1-3-5-2-patent-certification> <leaf> </leaf> </m1-3-5-2-patent-certification>
(0) Exclusivity Request	<m1-3-5-3-exclusivity-request> <leaf> </leaf> </m1-3-5-3-exclusivity-request>
End of Patent Exclusivity	</m1-3-5-patent-exclusivity>
End of Administrative Information	</m1-3-administrative-information>
0. Reference Section	<m1-4-references>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Letter of Authorization	<m1-4-1-letter-authorization> <leaf> </leaf> </m1-4-1-letter-authorization>
) Statement of Right to Reference	<m1-4-2-statement-right-reference> <leaf> </leaf> </m1-4-2-statement-right-reference>
) List of Authorized to Persons to Incorporate by Reference	<m1-4-3-list-authorized-persons-incorporate-reference> <leaf> </leaf> </m1-4-3-list-authorized-persons-incorporate-reference>
) Cross Reference to Other Applications	<m1-4-4-cross-reference-other-applications> <leaf> </leaf> </m1-4-4-cross-reference-other-applications>
End References	</m1-4-references>
0. Application Status Documentation	<m1-5-application-status>
) Withdrawal Request	<m1-5-1-withdrawal-request> <leaf> </leaf> </m1-5-1-withdrawal-request>
) Inactivation Request	<m1-5-2-inactivation-request> <leaf> </leaf> </m1-5-2-inactivation-request>
) Reactivation Request	<m1-5-3-reactivation-request> <leaf> </leaf> </m1-5-3-reactivation-request>
) Reinstatement Request	<m1-5-4-reinstatement-request> <leaf> </leaf> </m1-5-4-reinstatement-request>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Withdrawal of Unapproved NDA	<m1-5-5-withdrawal-unapproved-nda> <leaf> </leaf> </m1-5-5-withdrawal-unapproved-nda>
) Withdrawal of Listed Drug	<m1-5-6-withdrawal-of-listed-drug> <leaf> </leaf> </m1-5-6-withdrawal-of-listed-drug>
) Request for Withdrawal of Application Approval	<m1-5-7-request-withdrawal-application-approval> <leaf> </leaf> </m1-5-7-request-withdrawal-application-approval>
End Application Status	</m1-5-application-status>
0. Meetings	<m1-6-meetings>
) Meeting Request	<m1-6-1-meeting-request> <leaf> </leaf> </m1-6-1-meeting-request>
) Meeting Background Materials	<m1-6-2-meeting-background-materials> <leaf> </leaf> </m1-6-2-meeting-background-materials>
) Correspondence Regarding Meetings	<m1-6-3-correspondence-regarding-meetings> <leaf> </leaf> </m1-6-3-correspondence-regarding-meetings>
End Meetings	</m1-6-meetings>
0. Fast Track	<m1-7-fast-track>
) Fast Track Designation Request	<m1-7-1-fast-track-designation-request> <leaf> </leaf> </m1-7-1-fast-track-designation-request>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Fast Track Designation Withdrawal Request	<m1-7-2-fast-track-designation-withdrawal-request> <leaf> </leaf> </m1-7-2-fast-track-designation-withdrawal-request>
) Rolling Review Request	<m1-7-3-rolling-review-request> <leaf> </leaf> </m1-7-3-rolling-review-request>
End Fast Track	</m1-7-fast-track>
0. Special Protocol Assessment Request	<m1-8-special-protocol-assessment-request>
) Clinical Study	<m1-8-1-clinical-study> <leaf> </leaf> <m1-8-1-clinical-study>
) Carcinogenicity Study	<m1-8-2-carcinogenicity-study> <leaf> </leaf> <m1-8-2-carcinogenicity-study>
) Stability Study	<m1-8-3-stability-study> <leaf> </leaf> <m1-8-3-stability-study>
End Special Protocol	</m1-8-special-protocol-assessment-request>
0. Pediatric Administrative Information	<m1-9-pediatric-administrative-information>
) Request for Waiver of Pediatric Studies	<m1-9-1-request-waiver-pediatric-studies> <leaf> </leaf> </m1-9-1-request-waiver-pediatric-studies>
) Request for Deferral of Pediatric Studies	<m1-9-2-request-deferral-pediatric-studies> <leaf> </leaf> </m1-9-2-request-deferral-pediatric-studies>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Request for Pediatric Exclusivity Determination	<m1-9-3-request-pediatric-exclusivity-determination> <leaf> </leaf> </m1-9-3-request-pediatric-exclusivity-determination>
) Proposed Pediatric Study Request and amendments	<m1-9-4-proposed-pediatric-study-request-amendments> <leaf> </leaf> </m1-9-4-proposed-pediatric-study-request-amendments>
) Proposal for Written Agreement	<m1-9-5-proposal-written-agreement> <leaf> </leaf> </m1-9-5-proposal-written-agreement>
) Other Correspondence Regarding Pediatric Exclusivity or Study Plans	<m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans> <leaf> </leaf> </m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans>
End Pediatric	<\m1-9-pediatric-administrative-information>
0. Dispute Resolution	<m1-10-dispute-resolution>
) Request for Dispute Resolution	<m1-10-1-request-for-dispute-resolution> <leaf> </leaf> </m1-10-1-request-for-dispute-resolution>
) Correspondence Related to Dispute Resolution	<m1-10-2-correspondence-related-to-dispute-resolution> <leaf> </leaf> </m1-10-2-correspondence-related-to-dispute-resolution>
End Dispute Resolution	</m1-10-dispute-resolution>
0. Information Not Covered Under Modules 2 to 5	<m1-11-information-amendment>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Quality Information Amendment	<m1-11-1-quality-information-amendment> <leaf> </leaf> </m1-11-1-quality-information-amendment>
) Safety Information Amendment	<m1-11-2-safety-information-amendment> <leaf> </leaf> </m1-11-2-safety-information-amendment>
) Efficacy Information Amendment	<m1-11-3-efficacy-information-amendment> <leaf> </leaf> </m1-11-3-efficacy-information-amendment>
) Multiple Module Information Amendments	<m1-11-4-multiple-module-information-amendments> <leaf> </leaf> </m1-11-4-multiple-module-information-amendments>
End Modules	</m1-11-information-amendment>
0. Other Correspondence	<m1-12-other-correspondence>
) Pre IND Correspondence	<m1-12-1-pre-ind-correspondence> <leaf> </leaf> </m1-12-1-pre-ind-correspondence>
) Request to Charge	<m1-12-2-request-charge> <leaf> </leaf> </m1-12-2-request-charge>
) Notification of Charging Under Treatment IND	<m1-12-3-notification-charging-under-treatment-ind> <leaf> </leaf> </m1-12-3-notification-charging-under-treatment-ind>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Request for Comments and Advice on an IND	<m1-12-4-request-comments-advice-ind> <leaf> </leaf> </m1-12-4-request-comments-advice-ind>
) Request for Waiver	<m1-12-5-request-waiver> <leaf> </leaf> </m1-12-5-request-waiver>
) Exemption from Informed Consent for Emergency Research	<m1-12-6-exemption-informed-consent-emergency-research> <leaf> </leaf> </m1-12-6-exemption-informed-consent-emergency-research>
) Public Disclosure Statement for Emergency Care Research	<m1-12-7-public-disclosure-statement-emergency-care-research> <leaf> </leaf> </m1-12-7-public-disclosure-statement-emergency-care-research>
) Correspondence Regarding Emergency Care Research	<m1-12-8-correspondence-regarding-emergency-care-research> <leaf> </leaf> </m1-12-8-correspondence-regarding-emergency-care-research>
) Notification of Discontinuation of Clinical Trial	<m1-12-9-notification-discontinuation-clinical-trial> <leaf> </leaf> </m1-12-9-notification-discontinuation-clinical-trial>
) Generic Drug Enforcement Act Statement	<m1-12-10-generic-drug-enforcement-act-statement> <leaf> </leaf> </m1-12-10-generic-drug-enforcement-act-statement>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Basis for Submission Statement	<m1-12-11-basis-submission-statement> <leaf> </leaf> </m1-12-11-basis-submission-statement>
) Comparison of Generic Drug and Reference Listed Drug	<m1-12-12-comparison-generic-drug-reference-listed-drug> <leaf> </leaf> </m1-12-12-comparison-generic-drug-reference-listed-drug>
) Request for Waiver For In Vivo Studies	<m1-12-13-request-waiver-in-vivo-studies> <leaf> </leaf> </m1-12-13-request-waiver-in-vivo-studies>
) Environmental Analysis	<m1-12-14-environmental-analysis> <leaf> </leaf> </m1-12-14-environmental-analysis>
) Request for Waiver of In Vivo Bioavailability Studies	<m1-12-15-request-waiver-in-vivo-bioavailability-studies> <leaf> </leaf> </m1-12-15-request-waiver-in-vivo-bioavailability-studies>
) Field Alert Reports	<m1-12-16-field-alert-reports> <leaf> </leaf> </m1-12-16-field-alert-reports>
End of correspondence	</m1-12-other-correspondence>
0. Annual Report	<m1-13-annual-report>
) Summary for Nonclinical Studies	<m1-13-1-summary-nonclinical-studies> <leaf> </leaf> </m1-13-1-summary-nonclinical-studies>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Summary for Clinical Pharmacology Information	<m1-13-2-summary-clinical-pharmacology-information> <leaf> </leaf> </m1-13-2-summary-clinical-pharmacology-information>
) Summary of Safety Information	<m1-13-3-summary-safety-information> <leaf> </leaf> </m1-13-3-summary-safety-information>
) Summary of Labeling Changes	<m1-13-4-summary-labeling-changes> <leaf> </leaf> </m1-13-4-summary-labeling-hanges>
) Summary of manufacturing changes	<m1-13-5-summary-of-manufacturing-changes> <leaf> </leaf> </m1-13-5-summary-of-manufacturing-changes>
) Summary of microbiological changes	<m1-13-6-summary-of-microbiological-changes> <leaf> </leaf> </m1-13-6-summary-of-microbiological-changes
) Summary of Other Significant New Information	<m1-13-7-summary-other-significant-new-information> <leaf> </leaf> </m1-13-7-summary-other-significant-new-information>
) Individual Study Information	<m1-13-8-individual-study-information> <leaf> </leaf> </m1-13-8-individual-study-information>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) General Investigational Plan	<m1-13-9-general-investigational-plan> <leaf> </leaf> </m1-13-9-general-investigational-plan>
) Foreign Marketing History	<m1-13-10-foreign-marketing-history> <leaf> </leaf> </m1-13-10-foreign-marketing-history>
) Distribution Data	<m1-13-11-distribution-data> <leaf> </leaf> </m1-13-11-distribution-data>
) Status of Postmarketing Study Commitments	<m1-13-12-status-postmarketing-study-commitments> <leaf> </leaf> </m1-13-12-status-postmarketing-study-commitments>
) Status of Other Postmarketing Studies	<m1-13-13-status-other-postmarketing-studies> <leaf> </leaf> </m1-13-13-status-other-postmarketing-studies>
) Log of Outstanding Regulatory Business	<m1-13-14-log-outstanding-regulatory-business> <leaf> </leaf> </m1-13-14-log-outstanding-regulatory-business>
End Annual Report	</m1-13-annual-report>
0. Labeling	<m1-14-labeling>
) Draft Labeling	<m1-14-1-draft-labeling> <leaf> </leaf> </m1-14-1-draft-labeling>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
(0) Draft Carton and Container Labels	<m1-14-1-1-draft-carton-container-labels> <leaf> </leaf> </m1-14-1-1-draft-carton-container-labels>
(0) Annotated Draft Labeling Text	<m1-14-1-2-annotated-draft-labeling-text> <leaf> </leaf> </m1-14-1-2-annotated-draft-labeling-text>
(0) Draft Labeling Text	<m1-14-1-3-draft-labeling-text> <leaf> </leaf> </m1-14-1-3-draft-labeling-text>
(0) Label Comprehension Studies	<m1-14-1-4-label-comprehension-studies> <leaf> </leaf> </m1-14-1-4-label-comprehension-studies>
(0) Labeling History	<m1-14-1-5-labeling-history> <leaf> </leaf> </m1-14-1-5-labeling-history>
) Final Labeling	<m1-14-2-final-labeling> </m1-14-2-final-labeling>
(0) Final Carton or Container Labels	<m1-14-2-1-final-carton-container-labels> <leaf> </leaf> </m1-14-2-1-final-carton-container-labels>
(0) Final Package Insert (package inserts, patient information, medication guides)	<m1-14-2-2-final-package-insert-package-inserts> <leaf> </leaf> </m1-14-2-2-final-package-insert-package-inserts>
(0) Final labeling Text	<m1-14-2-3-final-labeling-text> <leaf> </leaf> </m1-14-2-3-final-labeling-text>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
) Listed Drug Labeling	<m1-14-3-listed-drug-labeling> <leaf> </leaf> </m1-14-3-listed-drug-labeling>
(0) Annotated Comparison with Listed Drug	<m1-14-3-1-annotated-comparison-listed-drug> <leaf> </leaf> </m1-14-3-1-annotated-comparison-listed-drug>
(0) Approved Labeling Text for Listed Drug	<m1-14-3-2-approved-labeling-text-listed-drug> <leaf> </leaf> </m1-14-3-2-approved-labeling-text-listed-drug>
(0) Labeling Text for Reference Listed Drug	<m1-14-3-3-labeling-text-reference-listed-drug> <leaf> </leaf> </m1-14-3-3-labeling-text-reference-listed-drug>
) Investigational Drug Labeling	<m1-14-4-investigational-drug-labeling> <leaf> </leaf> </m1-14-4-investigational-drug-labeling>
(0) Investigational Brochure	<m1-14-4-1-investigational-brochure> <leaf> </leaf> </m1-14-4-1-investigational-brochure>
(0) Investigational Drug Labeling	<m1-14-4-2-investigational-drug-label> <leaf> </leaf> </m1-14-4-2-investigational-drug-label>
) Foreign Labeling	<m1-14-5-foreign-labeling> <leaf> </leaf> </m1-14-5-foreign-labeling>

Module 1 Heading	Heading element (leaf element abbreviated for clarity)
End Labeling	</m1-14-labeling>
0. Promotional Material	<m1-15-promotional-material> <leaf> </leaf> </m1-15-promotional-material>
0. Risk Management Plans	<m1-16-risk-management-plans> <leaf> </leaf> </m1-16-risk-management-plans>
End Regional Leafs	</m1-regional>

V. DOCUMENT TYPE DEFINITION (DTD)

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- ================== DTD INFORMATION ========================== -->
<!-- US-regional DTD Version 2-01  -->
<!-- ================== TOP LEVEL ELEMENTS ======================= -->
<!ENTITY % att " ID      ID     #IMPLIED
  xml:lang CDATA  #IMPLIED">
<!ELEMENT fda-regional:fda-regional (admin, m1-regional?)>
<!ATTLIST fda-regional:fda-regional
    xmlns:fda-regional CDATA #FIXED "http://www.ich.org/fda"
    xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
    xml:lang CDATA #IMPLIED
    dtd-version CDATA #FIXED "2.01"
>
<!-- ================== LEAF CONTENT ============================== -->
<!ELEMENT leaf (title, link-text?)>
<!ATTLIST leaf
    ID ID #REQUIRED
    application-version CDATA #IMPLIED
    version CDATA #IMPLIED
    font-library CDATA #IMPLIED
    operation (new | append | replace | delete) #REQUIRED
    modified-file CDATA #IMPLIED
    checksum CDATA #IMPLIED
    checksum-type CDATA #IMPLIED
    keywords CDATA #IMPLIED
    xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
    xlink:type CDATA #FIXED "simple"
    xlink:role CDATA #IMPLIED
    xlink:href CDATA #IMPLIED
    xlink:show (new | replace | embed | other | none) #IMPLIED
    xlink:actuate (onLoad | onRequest | other | none) #IMPLIED
```

```
    xml:lang CDATA #IMPLIED
>
<!ELEMENT title (#PCDATA)>
<!ATTLIST title
    ID ID #IMPLIED
>
<!ELEMENT link-text (#PCDATA | xref)*>
<!ATTLIST link-text
    ID ID #IMPLIED
>
<!ELEMENT xref EMPTY>
<!ATTLIST xref
    ID ID #IMPLIED
    xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
    xlink:type CDATA #FIXED "simple"
    xlink:role CDATA #IMPLIED
    xlink:title CDATA #REQUIRED
    xlink:href CDATA #REQUIRED
    xlink:show (new | replace | embed | other | none) #IMPLIED
    xlink:actuate (onLoad | onRequest | other | none) #IMPLIED
>
<!ELEMENT node-extension (title, (leaf | node-extension)+)>
<!ATTLIST node-extension
    ID ID #IMPLIED
    xml:lang CDATA #IMPLIED
>
<!-- ================== ADMIN ================================== -->
<!ELEMENT admin (applicant-info, product-description, application-information)>
<!-- ********************* Applicant Information ******************** -->
<!ELEMENT applicant-info (company-name, date-of-submission)>
<!ELEMENT company-name (#PCDATA)>
<!ELEMENT date-of-submission (date)>
<!ELEMENT date (#PCDATA)>
<!ATTLIST date
    format (yyyymmdd) #REQUIRED
>
<!-- ********************* Product Description ********************** -->
<!ELEMENT product-description (application-number, prod-name+)>
<!ELEMENT application-number (#PCDATA)>
<!ELEMENT prod-name (#PCDATA)>
<!ATTLIST prod-name
    type (established | proprietary | chemical | code) #REQUIRED
>
<!-- ********************* Application Information ****************** -->
<!ELEMENT application-information (submission)>
<!ATTLIST application-information
```

```
    application-type (nda | anda | bla | dmf | ind | master-file) #REQUIRED
>
<!ELEMENT submission (sequence-number, related-sequence-number*)>
<!ATTLIST submission
    submission-type (
        original-application |
        amendment |
        resubmission |
        presubmission |
        annual-report |
        establishment-description-supplement |
        efficacy-supplement | labeling-supplement |
        chemistry-manufacturing-controls-supplement |
        other) #REQUIRED
>
<!ELEMENT sequence-number (#PCDATA)>
<!ELEMENT related-sequence-number (#PCDATA)>
<!-- ================= M1 REGIONAL STRUCTURE ==================== -->
<!ELEMENT m1-regional (
        m1-1-forms?,
        m1-2-cover-letters?,
        m1-3-administrative-information?,
        m1-4-references?,
        m1-5-application-status?,
        m1-6-meetings?,
        m1-7-fast-track?,
        m1-8-special-protocol-assessment-request?,
        m1-9-pediatric-administrative-information?,
        m1-10-dispute-resolution?,
        m1-11-information-amendment?,
        m1-12-other-correspondence?,
        m1-13-annual-report?,
        m1-14-labeling?,
        m1-15-promotional-material?,
        m1-16-risk-management-plans?)>
<!ATTLIST m1-regional
    %att;
>
<!-- ================= FORMS ================================== -->
<!ELEMENT m1-1-forms (
        m1-1-1-fda-form-1571?,
        m1-1-2-fda-form-356h?,
        m1-1-3-fda-form-3397?,
        m1-1-4-fda-form-2252?,
        m1-1-5-fda-form-2253?,
        m1-1-6-fda-form-2567?)>
```

```
<!ATTLIST m1-1-forms
    %att;
>
<!ELEMENT m1-1-1-fda-form-1571 ((leaf | node-extension)*)>
<!ATTLIST m1-1-1-fda-form-1571
    %att;
>
<!ELEMENT m1-1-2-fda-form-356h ((leaf | node-extension)*)>
<!ATTLIST m1-1-2-fda-form-356h
    %att;
>
<!ELEMENT m1-1-3-fda-form-3397 ((leaf | node-extension)*)>
<!ATTLIST m1-1-3-fda-form-3397
    %att;
>
<!ELEMENT m1-1-4-fda-form-2252 ((leaf | node-extension)*)>
<!ATTLIST m1-1-4-fda-form-2252
    %att;
>
<!ELEMENT m1-1-5-fda-form-2253 ((leaf | node-extension)*)>
<!ATTLIST m1-1-5-fda-form-2253
    %att;
>
<!ELEMENT m1-1-6-fda-form-2567 ((leaf | node-extension)*)>
<!ATTLIST m1-1-6-fda-form-2567
    %att;
>
<!-- ================= COVER LETTERS ============================ -->
<!ELEMENT m1-2-cover-letters ((leaf | node-extension)*)>
<!ATTLIST m1-2-cover-letters
    %att;
>
<!-- ================== ADMINISTRATIVE INFORMATION ============== -->
<!ELEMENT m1-3-administrative-information (
        m1-3-1-applicant-information*,
        m1-3-2-field-copy-certification*,
        m1-3-3-debarment-certification*,
        m1-3-4-financial-certification-disclosure*,
        m1-3-5-patent-exclusivity*)>
<!ATTLIST m1-3-administrative-information
    %att;
>
<!ELEMENT m1-3-1-applicant-information (
        m1-3-1-1-change-of-address-or-corporate-name*,
        m1-3-1-2-change-contact-agent*,
        m1-3-1-3-change-in-sponsor*,
```

```
        m1-3-1-4-transfer-obligation*,
        m1-3-1-5-change-application-ownership*)>
<!ATTLIST m1-3-1-applicant-information
    %att;
>
<!ELEMENT m1-3-1-1-change-of-address-or-corporate-name
    ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-1-change-of-address-or-corporate-name
    %att;
>
<!ELEMENT m1-3-1-2-change-contact-agent ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-2-change-contact-agent
    %att;
>
<!ELEMENT m1-3-1-3-change-in-sponsor ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-3-change-in-sponsor
    %att;
>
<!ELEMENT m1-3-1-4-transfer-obligation ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-4-transfer-obligation
    %att;
>
<!ELEMENT m1-3-1-5-change-application-ownership ((leaf | node-extension)*)>
<!ATTLIST m1-3-1-5-change-application-ownership
    %att;
>
<!-- ================== FIELD COPY CERTIFICATION ================ -->
<!ELEMENT m1-3-2-field-copy-certification ((leaf | node-extension)*)>
<!ATTLIST m1-3-2-field-copy-certification
    %att;
>
<!-- ================ DEBARMENT CERTIFICATION ================= -->
<!ELEMENT m1-3-3-debarment-certification ((leaf | node-extension)*)>
<!ATTLIST m1-3-3-debarment-certification
    %att;
>
<!-- ================= FINANCIAL CERTIFICATION DISCLOSURE ======= -->
<!ELEMENT m1-3-4-financial-certification-disclosure ((leaf | node-extension)*)>
<!ATTLIST m1-3-4-financial-certification-disclosure
    %att;
>
<!-- ==================== PATENT EXCLUSIVITIY ===================== --
>
<!ELEMENT m1-3-5-patent-exclusivity (
        m1-3-5-1-patent-information*,
        m1-3-5-2-patent-certification*,
```

```
        m1-3-5-3-exclusivity-request*)>
<!ATTLIST m1-3-5-patent-exclusivity
    %att;
>
<!ELEMENT m1-3-5-1-patent-information ((leaf | node-extension)*)>
<!ATTLIST m1-3-5-1-patent-information
    %att;
>
<!ELEMENT m1-3-5-2-patent-certification ((leaf | node-extension)*)>
<!ATTLIST m1-3-5-2-patent-certification
    %att;
>
<!ELEMENT m1-3-5-3-exclusivity-request ((leaf | node-extension)*)>
<!ATTLIST m1-3-5-3-exclusivity-request
    %att;
>
<!-- ================= REFERENCES ================================ -->
<!ELEMENT m1-4-references (
        m1-4-1-letter-authorization*,
        m1-4-2-statement-right-reference*,
        m1-4-3-list-of-authorized-persons-to-incorporate-by-reference*,
        m1-4-4-cross-reference-other-applications*)>
<!ATTLIST m1-4-references
    %att;
>
<!ELEMENT m1-4-1-letter-authorization ((leaf | node-extension)*)>
<!ATTLIST m1-4-1-letter-authorization
    %att;
>
<!ELEMENT m1-4-2-statement-right-reference ((leaf | node-extension)*)>
<!ATTLIST m1-4-2-statement-right-reference
    %att;
>
<!ELEMENT m1-4-3-list-of-authorized-persons-to-incorporate-by-reference
    ((leaf | node-extension)*)>
<!ATTLIST m1-4-3-list-of-authorized-persons-to-incorporate-by-reference
    %att;
>
<!ELEMENT m1-4-4-cross-reference-other-applications ((leaf | node-extension)*)>
<!ATTLIST m1-4-4-cross-reference-other-applications
    %att;
>
<!-- ================== APPLICATION STATUS ======================== -->
<!ELEMENT m1-5-application-status (
        m1-5-1-withdrawal-request*,
        m1-5-2-inactivation-request*,
```

```
        m1-5-3-reactivation-request*,
        m1-5-4-reinstatement-request*,
        m1-5-5-withdrawal-unapproved-nda*,
        m1-5-6-withdrawal-of-listed-drug*,
        m1-5-7-request-withdrawal-application-approval*)>
<!ATTLIST m1-5-application-status
    %att;
>
<!ELEMENT m1-5-1-withdrawal-request ((leaf | node-extension)*)>
<!ATTLIST m1-5-1-withdrawal-request
    %att;
>
<!ELEMENT m1-5-2-inactivation-request ((leaf | node-extension)*)>
<!ATTLIST m1-5-2-inactivation-request
    %att;
>
<!ELEMENT m1-5-3-reactivation-request ((leaf | node-extension)*)>
<!ATTLIST m1-5-3-reactivation-request
    %att;
>
<!ELEMENT m1-5-4-reinstatement-request ((leaf | node-extension)*)>
<!ATTLIST m1-5-4-reinstatement-request
    %att;
>
<!ELEMENT m1-5-5-withdrawal-unapproved-nda ((leaf | node-extension)*)>
<!ATTLIST m1-5-5-withdrawal-unapproved-nda
    %att;
>
<!ELEMENT m1-5-6-withdrawal-of-listed-drug ((leaf | node-extension)*)>
<!ATTLIST m1-5-6-withdrawal-of-listed-drug
    %att;
>
<!ELEMENT m1-5-7-request-withdrawal-application-approval ((leaf | node-extension)*)>
<!ATTLIST m1-5-7-request-withdrawal-application-approval
    %att;
>
<!-- ================= MEETINGS ================================= -->
<!ELEMENT m1-6-meetings (m1-6-1-meeting-request*, m1-6-2-meeting-background-
materials*, m1-6-3-correspondence-regarding-meetings*)>
<!ATTLIST m1-6-meetings
    %att;
>
<!ELEMENT m1-6-1-meeting-request ((leaf | node-extension)*)>
<!ATTLIST m1-6-1-meeting-request
    %att;
>
```

```
<!ELEMENT m1-6-2-meeting-background-materials ((leaf | node-extension)*)>
<!ATTLIST m1-6-2-meeting-background-materials
    %att;
>
<!ELEMENT m1-6-3-correspondence-regarding-meetings ((leaf | node-extension)*)>
<!ATTLIST m1-6-3-correspondence-regarding-meetings
    %att;
>
<!-- ================== FAST TRACK ============================== -->
<!ELEMENT m1-7-fast-track (
        m1-7-1-fast-track-designation-request*,
        m1-7-2-fast-track-designation-withdrawal-request*,
        m1-7-3-rolling-review-request*)>
<!ATTLIST m1-7-fast-track
    %att;
>
<!ELEMENT m1-7-1-fast-track-designation-request ((leaf | node-extension)*)>
<!ATTLIST m1-7-1-fast-track-designation-request
    %att;
>
<!ELEMENT m1-7-2-fast-track-designation-withdrawal-request
    ((leaf | node-extension)*)>
<!ATTLIST m1-7-2-fast-track-designation-withdrawal-request
    %att;
>
<!ELEMENT m1-7-3-rolling-review-request ((leaf | node-extension)*)>
<!ATTLIST m1-7-3-rolling-review-request
    %att;
>
<!-- ================ SPECIAL PROTOCOL ASSESSMENT REQUEST ====== -->
<!ELEMENT m1-8-special-protocol-assessment-request (
        m1-8-1-clinical-study*,
        m1-8-2-carcinogenicity-study*,
        m1-8-3-stability-study*)>
<!ATTLIST m1-8-special-protocol-assessment-request
    %att;
>
<!ELEMENT m1-8-1-clinical-study ((leaf | node-extension)*)>
<!ATTLIST m1-8-1-clinical-study
    %att;
>
<!ELEMENT m1-8-2-carcinogenicity-study ((leaf | node-extension)*)>
<!ATTLIST m1-8-2-carcinogenicity-study
    %att;
>
<!ELEMENT m1-8-3-stability-study ((leaf | node-extension)*)>
```

```
<!ATTLIST m1-8-3-stability-study
    %att;
>
<!-- ================== PEDIATRIC ADMINISTRATIVE INFORMATION ===== -->
<!ELEMENT m1-9-pediatric-administrative-information (
        m1-9-1-request-waiver-pediatric-studies*,
        m1-9-2-request-deferral-pediatric-studies*,
        m1-9-3-request-pediatric-exclusivity-determination*,
        m1-9-4-proposed-pediatric-study-request-amendments*,
        m1-9-5-proposal-written-agreement*,
        m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans*)>
<!ATTLIST m1-9-pediatric-administrative-information
    %att;
>
<!ELEMENT m1-9-1-request-waiver-pediatric-studies ((leaf | node-extension)*)>
<!ATTLIST m1-9-1-request-waiver-pediatric-studies
    %att;
>
<!ELEMENT m1-9-2-request-deferral-pediatric-studies ((leaf | node-extension)*)>
<!ATTLIST m1-9-2-request-deferral-pediatric-studies
    %att;
>
<!ELEMENT m1-9-3-request-pediatric-exclusivity-determination
    ((leaf | node-extension)*)>
<!ATTLIST m1-9-3-request-pediatric-exclusivity-determination
    %att;
>
<!ELEMENT m1-9-4-proposed-pediatric-study-request-amendments
    ((leaf | node-extension)*)>
<!ATTLIST m1-9-4-proposed-pediatric-study-request-amendments
    %att;
>
<!ELEMENT m1-9-5-proposal-written-agreement ((leaf | node-extension)*)>
<!ATTLIST m1-9-5-proposal-written-agreement
    %att;
>
<!ELEMENT m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans
    ((leaf | node-extension)*)>
<!ATTLIST m1-9-6-other-correspondence-regarding-pediatric-exclusivity-study-plans
    %att;
>
<!-- ================== DISPUTE RESOLUTION ====================== -->
<!ELEMENT m1-10-dispute-resolution (
        m1-10-1-request-for-dispute-resolution*,
        m1-10-2-correspondence-related-to-dispute-resolution*)>
<!ATTLIST m1-10-dispute-resolution
```

```
    %att;
>
<!ELEMENT m1-10-1-request-for-dispute-resolution ((leaf | node-extension)*)>
<!ATTLIST m1-10-1-request-for-dispute-resolution
    %att;
>
<!ELEMENT m1-10-2-correspondence-related-to-dispute-resolution ((leaf | node-extension)*)>
<!ATTLIST m1-10-2-correspondence-related-to-dispute-resolution
    %att;
>
<!-- ================ INFORMATION ADMENDMENT ================== -->
<!ELEMENT m1-11-information-amendment (
        m1-11-1-quality-information-amendment*,
        m1-11-2-safety-information-amendment*,
        m1-11-3-efficacy-information-amendment*,
        m1-11-4-multiple-module-information-amendments*)>
<!ATTLIST m1-11-information-amendment
    %att;
>
<!ELEMENT m1-11-1-quality-information-amendment ((leaf | node-extension)*)>
<!ATTLIST m1-11-1-quality-information-amendment
    %att;
>
<!ELEMENT m1-11-2-safety-information-amendment ((leaf | node-extension)*)>
<!ATTLIST m1-11-2-safety-information-amendment
    %att;
>
<!ELEMENT m1-11-3-efficacy-information-amendment ((leaf | node-extension)*)>
<!ATTLIST m1-11-3-efficacy-information-amendment
    %att;
>
<!ELEMENT m1-11-4-multiple-module-information-amendments
    ((leaf | node-extension)*)>
<!ATTLIST m1-11-4-multiple-module-information-amendments
    %att;
>
<!-- ================ OTHER CORRESPONDENCE ==================== -->
<!ELEMENT m1-12-other-correspondence (
        m1-12-1-pre-ind-correspondence*,
        m1-12-2-request-charge*,
        m1-12-3-notification-charging-under-treatment-ind*,
        m1-12-4-request-comments-advice-ind*,
        m1-12-5-request-waiver*,
        m1-12-6-exemption-informed-consent-emergency-research*,
        m1-12-7-public-disclosure-statement-emergency-care-research*,
        m1-12-8-correspondence-regarding-emergency-care-research*,
```

```
        m1-12-9-notification-discontinuation-clinical-trial*,
        m1-12-10-generic-drug-enforcement-act-statement*,
        m1-12-11-basis-submission-statement*,
        m1-12-12-comparison-generic-drug-reference-listed-drug*,
        m1-12-13-request-waiver-in-vivo-studies*,
        m1-12-14-environmental-analysis*,
        m1-12-15-request-waiver-in-vivo-bioavailability-studies*,
        m1-12-16-field-alert-reports*)>
<!ATTLIST m1-12-other-correspondence
    %att;
>
<!ELEMENT m1-12-1-pre-ind-correspondence ((leaf | node-extension)*)>
<!ATTLIST m1-12-1-pre-ind-correspondence
    %att;
>
<!ELEMENT m1-12-2-request-charge ((leaf | node-extension)*)>
<!ATTLIST m1-12-2-request-charge
    %att;
>
<!ELEMENT m1-12-3-notification-charging-under-treatment-ind
    ((leaf | node-extension)*)>
<!ATTLIST m1-12-3-notification-charging-under-treatment-ind
    %att;
>
<!ELEMENT m1-12-4-request-comments-advice-ind ((leaf | node-extension)*)>
<!ATTLIST m1-12-4-request-comments-advice-ind
    %att;
>
<!ELEMENT m1-12-5-request-waiver ((leaf | node-extension)*)>
<!ATTLIST m1-12-5-request-waiver
    %att;
>
<!ELEMENT m1-12-6-exemption-informed-consent-emergency-research
    ((leaf | node-extension)*)>
<!ATTLIST m1-12-6-exemption-informed-consent-emergency-research
    %att;
>
<!ELEMENT m1-12-7-public-disclosure-statement-emergency-care-research
    ((leaf | node-extension)*)>
<!ATTLIST m1-12-7-public-disclosure-statement-emergency-care-research
    %att;
>
<!ELEMENT m1-12-8-correspondence-regarding-emergency-care-research
    ((leaf | node-extension)*)>
<!ATTLIST m1-12-8-correspondence-regarding-emergency-care-research
    %att;
```

```
>
<!ELEMENT m1-12-9-notification-discontinuation-clinical-trial ((leaf | node-extension)*)>
<!ATTLIST m1-12-9-notification-discontinuation-clinical-trial
    %att;
>
<!ELEMENT m1-12-10-generic-drug-enforcement-act-statement
    ((leaf | node-extension)*)>
<!ATTLIST m1-12-10-generic-drug-enforcement-act-statement
    %att;
>
<!ELEMENT m1-12-11-basis-submission-statement ((leaf | node-extension)*)>
<!ATTLIST m1-12-11-basis-submission-statement
    %att;
>
<!ELEMENT m1-12-12-comparison-generic-drug-reference-listed-drug
    ((leaf | node-extension)*)>
<!ATTLIST m1-12-12-comparison-generic-drug-reference-listed-drug
    %att;
>
<!ELEMENT m1-12-13-request-waiver-in-vivo-studies ((leaf | node-extension)*)>
<!ATTLIST m1-12-13-request-waiver-in-vivo-studies
    %att;
>
<!ELEMENT m1-12-14-environmental-analysis ((leaf | node-extension)*)>
<!ATTLIST m1-12-14-environmental-analysis
    %att;
>
<!ELEMENT m1-12-15-request-waiver-in-vivo-bioavailability-studies
    ((leaf | node-extension)*)>
<!ATTLIST m1-12-15-request-waiver-in-vivo-bioavailability-studies
    %att;
>
<!ELEMENT m1-12-16-field-alert-reports ((leaf | node-extension)*)>
<!ATTLIST m1-12-16-field-alert-reports
    %att;
>
<!-- ================ ANNUAL REPORT ============================ -->
<!ELEMENT m1-13-annual-report (
        m1-13-1-summary-nonclinical-studies*,
        m1-13-2-summary-clinical-pharmacology-information*,
        m1-13-3-summary-safety-information*,
        m1-13-4-summary-labeling-changes*,
        m1-13-5-summary-manufacturing-changes*,
        m1-13-6-summary-microbiological-changes*,
        m1-13-7-summary-other-significant-new-information*,
        m1-13-8-individual-study-information*,
```

```
        m1-13-9-general-investigational-plan*,
        m1-13-10-foreign-marketing-history*,
        m1-13-11-distribution-data*,
        m1-13-12-status-postmarketing-study-commitments*,
        m1-13-13-status-other-postmarketing-studies*,
        m1-13-14-log-outstanding-regulatory-business*)>
<!ATTLIST m1-13-annual-report
    %att;
>
<!ELEMENT m1-13-1-summary-nonclinical-studies ((leaf | node-extension)*)>
<!ATTLIST m1-13-1-summary-nonclinical-studies
    %att;
>
<!ELEMENT m1-13-2-summary-clinical-pharmacology-information
    ((leaf | node-extension)*)>
<!ATTLIST m1-13-2-summary-clinical-pharmacology-information
    %att;
>
<!ELEMENT m1-13-3-summary-safety-information ((leaf | node-extension)*)>
<!ATTLIST m1-13-3-summary-safety-information
    %att;
>
<!ELEMENT m1-13-4-summary-labeling-changes ((leaf | node-extension)*)>
<!ATTLIST m1-13-4-summary-labeling-changes
    %att;
>
<!ELEMENT m1-13-5-summary-manufacturing-changes ((leaf | node-extension)*)>
<!ATTLIST m1-13-5-summary-manufacturing-changes
    %att;
>
<!ELEMENT m1-13-6-summary-microbiological-changes ((leaf | node-extension)*)>
<!ATTLIST m1-13-6-summary-microbiological-changes
    %att;
>
<!ELEMENT m1-13-7-summary-other-significant-new-information
    ((leaf | node-extension)*)>
<!ATTLIST m1-13-7-summary-other-significant-new-information
    %att;
>
<!ELEMENT m1-13-8-individual-study-information ((leaf | node-extension)*)>
<!ATTLIST m1-13-8-individual-study-information
    %att;
>
<!ELEMENT m1-13-9-general-investigational-plan ((leaf | node-extension)*)>
<!ATTLIST m1-13-9-general-investigational-plan
    %att;
```

```
>
<!ELEMENT m1-13-10-foreign-marketing-history ((leaf | node-extension)*)>
<!ATTLIST m1-13-10-foreign-marketing-history
    %att;
>
<!ELEMENT m1-13-11-distribution-data ((leaf | node-extension)*)>
<!ATTLIST m1-13-11-distribution-data
    %att;
>
<!ELEMENT m1-13-12-status-postmarketing-study-commitments
    ((leaf | node-extension)*)>
<!ATTLIST m1-13-12-status-postmarketing-study-commitments
    %att;
>
<!ELEMENT m1-13-13-status-other-postmarketing-studies ((leaf | node-extension)*)>
<!ATTLIST m1-13-13-status-other-postmarketing-studies
    %att;
>
<!ELEMENT m1-13-14-log-outstanding-regulatory-business ((leaf | node-extension)*)>
<!ATTLIST m1-13-14-log-outstanding-regulatory-business
    %att;
>
<!-- ==================== LABELING ================================= --
>
<!ELEMENT m1-14-labeling (
        m1-14-1-draft-labeling*,
        m1-14-2-final-labeling*,
        m1-14-3-listed-drug-labeling*,
        m1-14-4-investigational-drug-labeling*,
        m1-14-5-foreign-labeling*)>
<!ATTLIST m1-14-labeling
    %att;
>
<!ELEMENT m1-14-1-draft-labeling (
        m1-14-1-1-draft-carton-container-labels*,
        m1-14-1-2-annotated-draft-labeling-text*,
        m1-14-1-3-draft-labeling-text*,
        m1-14-1-4-label-comprehension-studies*,
        m1-14-1-5-labeling-history*)>
<!ATTLIST m1-14-1-draft-labeling
    %att;
>
<!ELEMENT m1-14-1-1-draft-carton-container-labels ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-1-draft-carton-container-labels
    %att;
>
```

```
<!ELEMENT m1-14-1-2-annotated-draft-labeling-text ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-2-annotated-draft-labeling-text
   %att;
>
<!ELEMENT m1-14-1-3-draft-labeling-text ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-3-draft-labeling-text
   %att;
>
<!ELEMENT m1-14-1-4-label-comprehension-studies ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-4-label-comprehension-studies
   %att;
>
<!ELEMENT m1-14-1-5-labeling-history ((leaf | node-extension)*)>
<!ATTLIST m1-14-1-5-labeling-history
   %att;
>
<!ELEMENT m1-14-2-final-labeling (
        m1-14-2-1-final-carton-container-labels*,
        m1-14-2-2-final-package-insert-package-inserts*,
        m1-14-2-3-final-labeling-text*)>
<!ATTLIST m1-14-2-final-labeling
   %att;
>
<!ELEMENT m1-14-2-1-final-carton-container-labels ((leaf | node-extension)*)>
<!ATTLIST m1-14-2-1-final-carton-container-labels
   %att;
>
<!ELEMENT m1-14-2-2-final-package-insert-package-inserts ((leaf | node-extension)*)>
<!ATTLIST m1-14-2-2-final-package-insert-package-inserts
   %att;
>
<!ELEMENT m1-14-2-3-final-labeling-text ((leaf | node-extension)*)>
<!ATTLIST m1-14-2-3-final-labeling-text
   %att;
>
<!ELEMENT m1-14-3-listed-drug-labeling (
        m1-14-3-1-annotated-comparison-listed-drug*,
        m1-14-3-2-approved-labeling-text-listed-drug*,
        m1-14-3-3-labeling-text-reference-listed-drug*)>
<!ATTLIST m1-14-3-listed-drug-labeling
   %att;
>
<!ELEMENT m1-14-3-1-annotated-comparison-listed-drug ((leaf | node-extension)*)>
<!ATTLIST m1-14-3-1-annotated-comparison-listed-drug
   %att;
>
```

```
<!ELEMENT m1-14-3-2-approved-labeling-text-listed-drug ((leaf | node-extension)*)>
<!ATTLIST m1-14-3-2-approved-labeling-text-listed-drug
    %att;
>
<!ELEMENT m1-14-3-3-labeling-text-reference-listed-drug ((leaf | node-extension)*)>
<!ATTLIST m1-14-3-3-labeling-text-reference-listed-drug
    %att;
>
<!ELEMENT m1-14-4-investigational-drug-labeling (
        m1-14-4-1-investigational-brochure*,
        m1-14-4-2-investigational-drug-label*)>
<!ATTLIST m1-14-4-investigational-drug-labeling
    %att;
>
<!ELEMENT m1-14-4-1-investigational-brochure ((leaf | node-extension)*)>
<!ATTLIST m1-14-4-1-investigational-brochure
    %att;
>
<!ELEMENT m1-14-4-2-investigational-drug-label ((leaf | node-extension)*)>
<!ATTLIST m1-14-4-2-investigational-drug-label
    %att;
>
<!ELEMENT m1-14-5-foreign-labeling ((leaf | node-extension)*)>
<!ATTLIST m1-14-5-foreign-labeling
    %att;
>
<!-- ================= PROMOTIONAL MATERIAL ===================== -->
<!ELEMENT m1-15-promotional-material ((leaf | node-extension)*)>
<!ATTLIST m1-15-promotional-material
    %att;
>
<!-- ================== RISK MANAGEMENT ======================== -->
<!ELEMENT m1-16-risk-management-plans ((leaf | node-extension)*)>
<!ATTLIST m1-16-risk-management-plans
    %att;
>
```