The Comprehensive Table of Contents Headings and Hierarchy

Revision History

Date	Version	Summary of Changes
2004-07	1.0	Original version
2005-06-16	1.1	Corrections and additions to the mapping tables
2005-07-06	1.2	Corrections to the headings
2012-06-01	2.0	Corrections and additions to the mapping tables based on major update to Module 1 specifications (Summary of Changes in Section C of Appendix 2)
2012-11-01	2.1	Modified the heading for 1.16 and added REMS and non-REMS sub-headings (Summary of Changes in Section B of Appendix 2)
2013-08-23	2.2	Added two new attributes for 1.15.2.1 (Summary of Changes in Section A of Appendix 2)
2014-02-07	2.3	Modified the heading for 1.15.1.5 (Summary of Changes in Section A of Appendix 2)
2017-04-17	2.3.1	Updated heading names under sections 4.2.1.1, 5.3.1.1, 5.3.5.3 to align with file tags in ICH valid values version 3.0.
2018-11-01	2.3.2	Fixed page numbering and updated content under sections 5.3.5.3 and 5.3.5.4

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Pre clinical study report
Synopsis
Study report body
Protocol or amendment
Signatures investigators
Audit certificates report
Statistical methods interim analysis plan
Inter-laboratory standardisation methods quality assurance
Publications based on study
Publications referenced in report
Compliance and drug concentration data

Data tabulation

Data tabulation dataset legacy
Data tabulation dataset send
Data tabulation data definition

Data listing dataset

Data listing dataset
Data listing data definition

Analysis datasets

Analysis dataset adam
Analysis dataset legacy
Analysis program
Analysis data definition

Safety report

4.2.1.2 Secondary pharmacodynamics

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related

information for headings

4.2.1.3 Safety pharmacology

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.1.4 Pharmacodynamic drug interactions

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.2 Pharmacokinetics

4.2.2.1 Analytical methods and validation reports

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.2.2 Absorption

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.2.3 Distribution

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.2.4 Metabolism

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See Primary pharmacodynamics Study report and related information for headings

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Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.3 Genotoxicity

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See Primary pharmacodynamics Study report and related information for headings

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4.2.3.4.2 Short or medium term studies

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4.2.3.5.2 Embryofetal development

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Legacy clinical study report
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Signatures investigators (E3 16.1.5)
List patients with batches (E316.1.6)
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Audit certificates report (E3 16.1.8)
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Publications referenced in report (E3 16.1.12)
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Individual efficacy response data (E3 16.2.6)
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Listing individual laboratory measurements by patient (E3

16.2.8)
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Site [identifier]
Available on request
Data tabulation
Data tabulation dataset legacy
Data tabulation dataset sdtm
Data tabulation data definition
Data listing dataset (E3 16.4)
Data listing dataset
Data listing data definition
Analysis datasets
Analysis dataset adam
Analysis dataset legacy
Analysis program
Analysis data definition
Annotated CRF
ECG
Image
Subject profiles
Safety report

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Study report [identification] and related information

Integrated analysis of safety

Iss

Analysis datasets

Analysis dataset adam
Analysis dataset legacy
Analysis program
Analysis data definition

Integrated analysis of efficacy

Ise

Analysis datasets

Analysis dataset adam
Analysis dataset legacy
Analysis program
Analysis data definition

5.3.5.4 Other Study reports and related information

Study report [identification] and related information

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Antibacterial

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Special pathogen

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Antiviral

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Postmarketing periodic adverse event drug experience report description

5.4 Literature references

Appendix I – Mapping Section

IND

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
312.23(a)(1)	Cover sheet (Form FDA–1571)	1	1.1	**Forms form-type=1571
FDAAA	Certification of compliance: Form FDA 3674	1	1.1	**Forms form-type=3674
BsUFA	Form FDA 3792: Biosimilar User Fee Cover Sheet	1	1.1	**Forms form-type=3792
312.31(b)(1)	Statement of the nature and purpose of the information amendment	1	1.2	Cover letters
	Change of address or corporate name NOTE: Includes DMF original address or corporate name or change in DMF address or corporate name	1	1.3.1.1	Change of address or corporate name
	Change in contact/agent NOTE: Includes DMF original contact/agent or change in DMF contact/agent	1	1.3.1.2	Change in contact/agent
	Change in ownership	1	1.3.1.3	Change in sponsor
312.52	Transfer of obligations to a contract research organization	1	1.3.1.4	Transfer of obligation
312.22(d)	General principles of the IND submission		1.4.1	Letter of authorization
312.23(b)	Written statement of authorization for references (copy of LOA received from DMF holders - submitted by BLA, NDA, or IND applicants)	1	1.4.2	Statement of right of reference

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
312.23(b) 312.23(a)(3)(ii)	Information previously submitted	1	1.4.4	Cross-reference to previously submitted information
312.38	Withdrawal of an IND	1	1.5.1	Withdrawal of an IND
312.45(a)	Request for Inactive status	1	1.5.2	Inactivation request
312.45(d)	Request to resume clinical investigation under an inactive IND	1	1.5.3	Reactivation request
	Reinstatement request	1	1.5.4	Reinstatement request
312.47 PDUFA Agreements	Meeting request	1	1.6.1	Meeting request
312.47 PDUFA Agreements	Meeting background material	1	1.6.2	Meeting background materials
312.47 PDUFA Agreements	Correspondence regarding a meeting	1	1.6.3	Correspondence regarding meetings
FDAMA	Fast track designation request	1	1.7.1	Fast track designation request
FDAMA	Fast track designation withdrawal request	1	1.7.2	Fast track designation withdrawal request
FDAMA	Rolling review request	1	1.7.3	Rolling review request
FDAMA	Correspondence regarding fast track/rolling review	1	1.7.4	Correspondence regarding fast track/rolling review
FDAMA	Special protocol assessment request: clinical study	1	1.8.1	Clinical study
PDUFA Agreements	Special protocol assessment request: carcinogenicity study	1	1.8.2	Carcinogenicity study
PDUFA Agreements	Special protocol assessment request: stability study	1	1.8.3	Stability study
	Animal efficacy study for approval under the animal rule	1	1.8.4.	Animal efficacy study for approval under the animal rule
PREA 312.47(b)(1)(iv)	Request for waiver of pediatric studies	1	1.9.1	Request for waiver of pediatric studies

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
PREA 312.82 312.47(b)(1)(iv)	Request for deferral of pediatric studies	1	1.9.2	Request for deferral of pediatric studies
BPCA	Proposed pediatric study request and amendments	1	1.9.4	Proposed pediatric study request and amendments
PREA BPCA	Correspondence regarding pediatric exclusivity or PREA requirements	1	1.9.6	Other correspondence regarding pediatric exclusivity or study plans
312.48	Scientific and medical disputes	1	1.10.1	Request for dispute resolution
312.48	Scientific and medical disputes	1	1.10.2	Correspondence related to dispute resolution
312.31	Information amendment: Chemistry - information not covered under Module 3	1	1.11.1	Quality information amendment
312.31	Information amendment: Toxicology - information not covered under Module 4	1	1.11.2	Nonclinical information amendment
312.31	Information amendment: Clinical - information not covered under Module 5	1	1.11.3	Clinical information amendment
312.31	Multiple Information amendment	1	1.11.4	Multiple module information amendment
312.82(a)	Pre-IND correspondence	1	1.12.1	Pre-IND correspondence
312.8(b)	Charging for investigational drugs under an IND	1	1.12.2	Request to charge for clinical trial
312.8(c)	Charging for investigational drugs under an IND	1	1.12.3	Request to charge for expanded access
312.31(b)(3)	Request for comment on information amendment	1	1.12.4	Request for comments and advice
312.41	Comment and advice on an IND	1	1.12.4	Request for comments and advice
312.10	Waivers (including PSUR waiver)	1	1.12.5	Request for a waiver

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
312.54	Exception from informed consent for research	1	1.12.6	Exception from informed consent for emergency research
312.54	Public disclosure – exception from informed consent for research	1	1.12.7	Public disclosure statement for exception from informed consent for emergency research
312.54	IRB disapproval of exception from informed consent for research	1	1.12.8	Correspondence regarding exception from informed consent for emergency research
312.31(a)(2)	Report regarding the discontinuation of a clinical investigation	1	1.12.9	Notification of discontinuation of clinical trial
312.23(a)(7)(iv)(e)	Environmental analysis requirements	1	1.12.14	Environmental analysis
316 Subpart C	Orphan Drug	1	1.12.17	Orphan drug designation
312.33(b)(6)	Annual Report: A list of preclinical studies…	1	1.13.1	Summary of nonclinical studies
312.33(b)(5)	Annual Report: A brief description of the drug's actions…	1	1.13.2	Summary of clinical pharmacology information
312.33(b)(1)	Annual Report: A narrative or tabular summary showing the most frequent and most serious adverse experiences by the body system	1	1.13.3	Summary of safety information
312.33(b)(2)	Annual Report: A summary of all IND safety reports…	1	1.13.3	Summary of safety information
312.33(b)(3)	Annual Report: A list of subjects who died…	1	1.13.3	Summary of safety information
312.33(b)(4)	Annual Report: A list of subjects who dropped out…	1	1.13.3	Summary of safety information

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
312.33(b)(7)	Annual Report: A summary of any significant manufacturing changes…	1	1.13.5	Summary of manufacturing changes
312.33(b)(7)	Annual Report: A summary of any significant microbiological changes…	1	1.13.6	Summary of microbiological changes
312.33(a)	Annual report individual study information	1	1.13.8	Individual study information
312.33(c)	Annual Report: A description of the general investigational plan…	1	1.13.9	General investigational plan
312.33(f)	Annual Report: A brief summary of significant foreign marketing developments…	1	1.13.10	Foreign marketing
312.33(g)	Annual Report: Log of outstanding business…(optional)	1	1.13.14	Log of outstanding regulatory business
	Development safety update report (DSUR)	1	1.13.15	Development safety update report (DSUR)
312.6	Draft labeling text	1	1.14.1.3	Draft labeling text
	Label comprehension studies	1	1.14.1.4	Label comprehension studies
312.23(a)(5)	Investigator brochure	1	1.14.4.1	Investigator brochure
312.33(d)	Annual Report: Investigators brochure…	1	1.14.4.1	Investigator brochure
312.23(a)(7)(iv)(d)	Labeling	1	1.14.4.2	Investigational drug labeling
	Foreign labeling	1	1.14.5	Foreign labeling
	Proprietary names	1	1.18	Proprietary names
Project BioShield Act of 2004	Emergency Use Authorization	1	1.19	Pre-EUA and EUA
312.23(a)(3)(iv)	A brief description of the overall plan…	1	1.20	General investigational plan for initial IND

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
312.23(a)(3)(i)	Introductory statement	2	2.2	Introduction to summary
312.23(a)(7)(a), (b) and (c)	Chemistry, manufacturing, and controls	2	2.3	Quality overall summary
312.23(a)(8)	Pharmacology and toxicology information	2	2.4	Nonclinical overview
312.23(a)(9)	Previous human experience	2	2.5	Clinical overview
312.23(a)(3)(ii-iii)	Introductory statement	2	2.5	Clinical overall summary
312.23(a)(8)	Pharmacology and toxicology information	2	2.6	Nonclinical written and tabulated summaries [use appropriate sections]
312.23(a)(9)	Previous human experience	2	2.7	Clinical summary [use appropriate sections]
312.23(a)(10)(i)	Drug dependence and abuse	2	2.7.4	Summary of Clinical Safety
312.23(a)(8)	Pharmacology and toxicology information	4	4.2	Study reports [use appropriate sections]
312.23(a)(9)	Previous human experience	5	5.3	Clinical study reports and related information [use appropriate sections]
312.30(a)	New protocol	5	5.3	Protocol [under specific study]
312.30(b)	Changes in protocol	5	5.3	Protocol [under specific study]
312.30(c)	New investigator	5	5.3	List and description of investigators and sites [under specific study]
312.23(a)(6)	Protocol	5	5.3	*Protocol [under specific study]
312.32	IND safety reports	5	5.3	*IND safety report [under specific study]
312.33(e)	Annual Report: A description of any significant Phase 1 protocol modifications made during the previous years and….	5	5.3	*Protocol [under the specific study]
312.320	Treatment protocol	5	5.3	*Protocol [under specific study]
312.120(b)(1)	Foreign clinical studies not conducted under the IND: Investigator's qualification	5	5.3	*List and description of investigators and sites [under specific study]

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
312.120(b)(2)	Foreign clinical studies not conducted under the IND: Research facility	5	5.3	*List and description of investigators and sites [under specific study]
312.120(b)(3)	Foreign clinical studies not conducted under the IND: Detailed summary	5	5.3	Use appropriate sections [under specific study]
312.120(a)(1)	Foreign clinical studies not conducted under the IND: Conformance with ethical principles	5	5.3	*List of IECs or IRBs and consent forms [under specific study]
312.23(a)(11)	Relevant information	1, 2, 3, 4, or 5	As needed	Use appropriate sections
312.23(c)	Material in a foreign language (English translations)	1, 2, 3, 4, or 5	As needed	Use appropriate sections
312.23(a)(10)(iv)	Other information	2, 3, 4, or 5	As needed	Use appropriate sections
312.23(a)(10)(ii)	Radioactive drugs	2, 4, or 5	As needed	Use appropriate sections
312.23(a)(7)(a), (b) and (c)	Chemistry, manufacturing and controls	3	As needed	Quality [use appropriate sections]
312.31(a)(1),	Information amendment: Chemistry	3	As needed	Use appropriate sections
312.120(b)(4)	Foreign clinical studies not conducted under the IND: A description of the drug substance and drug product	3	As needed	Use appropriate sections
312.31	Information amendment: Toxicology	4	As needed	Use appropriate sections
312.31	Information amendment: Clinical	5	As needed	Use appropriate sections
312.23(a)(2)	Table of contents	N/A	N/A	N/A

NDA and BLA

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.50(a) 601.2	Application Form FDA 356h	1	1.1	**Forms form-type=356h
PDUFA	User fee cover sheet: Form FDA 3397	1	1.1	**Forms form-type=3397
BsUFA	Form FDA 3792: Biosimilar User Fee Cover Sheet	1	1.1	**Forms form-type=3392
314.81(b)(2)	Annual report transmittal: Form FDA 2252	1	1.1	**Forms form-type=2252
314.81(b)(3)(i) 601.12(f)(4)	Transmittal of advertisements and promotional labeling: Form FDA 2253	1	1.1	**Forms form-type=2253
601.12 (f)	Transmittal of labels and circulars: Form FDA 2567	1	1.1	**Forms form-type=2567
	Cover letters	1	1.2	Cover letters
	Change of address or corporate name NOTE: Includes DMF original address or corporate name or change in DMF address or corporate name	1	1.3.1.1	Change of address or corporate name
	Change in contact/agent NOTE: Includes DMF original contact/agent or change in DMF contact/agent	1	1.3.1.2	Change in contact/agent
314.50(d)(5)(x)	Transfer of obligations to CRO	1	1.3.1.4	Transfer of obligation
314.72 601.4	Change in ownership of an application	1	1.3.1.5	Change in ownership of an application or reissuance of license
314.50(d)(1)(v)	Field copy certification	1	1.3.2	Field copy certification
GDEA	Debarment certification	1	1.3.3	Debarment certification

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.50(k) 601.2(a)	Financial certification and disclosure statement (Form FDA 3454 and Form FDA 3455)	1	1.3.4	Financial certification and disclosure
314.50(h) 314.53(e)	Patent Information (Form FDA 3542a and Form FDA 3542)	1	1.3.5.1	Patent information
314.50(i) 314.52(e)	Patent certification	1	1.3.5.2	Patent certification
314.50(j)	Claimed exclusivity	1	1.3.5.3	Exclusivity claim
FDAAA	Tropical disease priority review voucher	1	1.3.6	Tropical disease priority review voucher
314.420(d)	Incorporating DMF information by reference (authorization from DMF holder)	1	1.4.1	Letter of authorization
314.50(g)(1)	Written statement of authorization for references (copy of LOA received from DMF holders - submitted by BLA, NDA, or IND applicants)	1	1.4.2	Statement of right of reference
314.420(d)	List of authorized persons to incorporate by reference	1	1.4.3	List of authorized persons to incorporate by reference
314.50(g)(1)	Reference to information previously submitted	1	1.4.4	Cross-reference to previously submitted information
314.65	Withdrawal of an unapproved application	1	1.5.5	Withdrawal of an unapproved NDA, ANDA or Supplement
314.50	Withdrawal of listed drug	1	1.5.6	Withdrawal of listed drug
314.150(c)	Withdrawal of approval	1	1.5.7	Withdrawal of approval of an application or revocation of license
314.150 601.5	Withdrawal of approval by the FDA	1	1.5.7	Withdrawal of approval of an application or revocation of license
314.102	Communications: Meetings	1	1.6.1	Meeting request

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.102	Communications: Meetings	1	1.6.2	Meeting background materials
314.102	Communications: Meetings	1	1.6.3	Correspondence regarding meetings
FDAMA	Fast track designation request	1	1.7.1	Fast track designation request
FDAMA	Fast track designation withdrawal request	1	1.7.2	Fast track designation withdrawal request
FDAMA	Rolling review request	1	1.7.3	Rolling review request
FDAMA	Correspondence regarding fast track/rolling review	1	1.7.4	Correspondence regarding fast track/rolling review
PREA 314.55(c) 601.27(c)	Request for waiver of pediatric studies	1	1.9.1	Request for waiver of pediatric studies
PREA 314.55(b) 601.27(b)	Request for deferral of pediatric studies	1	1.9.2	Request for deferral of pediatric studies
BPCA	Request for pediatric exclusivity determination/Form FDA 3437	1	1.9.3	Request for pediatric exclusivity determination
BPCA	Proposed pediatric study request and amendments	1	1.9.4	Proposed pediatric study request and amendments
PREA BPCA	Correspondence regarding pediatric exclusivity or PREA requirements	1	1.9.6	Other correspondence regarding pediatric exclusivity or study plans
314.103(c)	Scientific and medical disputes	1	1.10.1	Request for dispute resolution
314.103(c)	Scientific and medical disputes	1	1.10.2	Correspondence related to dispute resolution
314.60	Amendment to an unapproved application: Chemistry (information not covered under Module 3)	1	1.11.1	Quality information amendment
314.60	Amendment to an unapproved application: Toxicology	1	1.11.2	Nonclinical information amendment

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
	(information not covered under Module 4)			
314.60	Amendment to an unapproved application: Clinical (information not covered under Module 5)	1	1.11.3	Clinical information amendment
314.60	Multiple information amendment:	1	1.11.4	Multiple module information amendment
	Request for comment and advice	1	1.12.4	Request for comments and advice
314.90 600.90	Waivers (including PSUR waiver)	1	1.12.5	Request for a waiver
GDEA	Generic drug enforcement act statement	1	1.12.10	Generic drug enforcement act statement
314.50(d)(1)(iii) 601.2	Environmental impact	1	1.12.14	Environmental analysis
320.22 (a)	Request for waiver of in vivo bioavailability studies	1	1.12.15	Request for waiver of in vivo bioavailability studies
314.81(b)(1)	Field alert reports	1	1.12.16	Field alert reports
316 Subpart C	Orphan drug	1	1.12.17	Orphan drug designation
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.1	Summary of nonclinical studies
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.2	Summary of clinical pharmacology information
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.3	Summary of safety information
314.81(b)(2)(i) 601.12(f)(3)	Annual Report: Summary	1	1.13.4	Summary of labeling changes
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.5	Summary of manufacturing changes
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.6	Summary of microbiological changes
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.7	Summary of other significant new

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
601.12(d)				information
314.81(b)(2)(ii)	Annual Report: Distribution data	1	1.13.11	Distribution data
314.81(b)(2)(vii) 601.70	Annual Report: Status report of clinical and nonclinical toxicology postmarketing study commitments	1	1.13.12	Status of postmarketing study commitments and requirements
314.81(b)(2)(viii)	Status report of other (chemistry, manufacturing, controls) postmarketing study commitments	1	1.13.13	Status of other postmarketing studies and requirements
314.81(b)(2)(ix)	Annual Report: Log of outstanding regulatory business	1	1.13.14	Log of outstanding regulatory business
314.50(e)(2)(ii) 601.14	Copies of the labeling and all labeling for the drug product	1	1.14	Use appropriate sections
314.81(b)(2)(iii) 601.14(f)(3)	Annual Report: Labeling	1	1.14	Use appropriate sections
314.50 601.14	Draft carton and container labels	1	1.14.1.1	Draft carton and container labels
314.50(c)(2)(i)	The proposed text of the labeling with annotations	1	1.14.1.2	Annotated draft labeling text
314.50(e)(2)(ii) 601.2 601.14	Draft labeling text	1	1.14.1.3	Draft labeling text
	Label comprehension studies	1	1.14.1.4	Label comprehension studies
	Labeling history	1	1.14.1.5	Labeling history
314.50(e)(2)(ii) 601.2	Final carton or container labels	1	1.14.2.1	Final carton or container labels
314.50(e)(2)(ii) 601.2; 601.14	Final package insert (package inserts, patient information, medication guides)	1	1.14.2.2	Final package insert (package inserts, patient information, medication guides)
314.50(e)(2)(ii) 601.2; 601.14	Final labeling text	1	1.14.2.3	Final labeling text

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
	Foreign labeling	1	1.14.5	Foreign labeling
314.81(b)(3)(i) 601.12(f)(4)	Product labeling for 2253 submissions (if applicable)	1	1.14.6	Product labeling for 2253 submissions
314.81(b)(3)(i) 601.12(f)(4) 314.550 601.45 202.1(j)(4) 314.640 601.94 202.1	Regulations related to promotional materials [use appropriate sections]	1	1.15	Promotional material **[promotional-material-audience-type]
202.1(j)(4)	Request for advisory comments on launch materials	1	1.15.1.1	Request for advisory comments on launch materials
202.1(j)(4)	Request for advisory comments on non-launch materials	1	1.15.1.2	Request for advisory comments on non-launch materials
314.550 601.45	Presubmission of launch promotional materials for accelerated approval of products for serious or life-threatening illnesses	1	1.15.1.3	Presubmission of launch promotional materials for accelerated approval products
314.640 601.94	Presubmission of launch promotional materials for products approved when human efficacy studies are not ethical or feasible	1	1.15.1.3	Presubmission of launch promotional materials for accelerated approval products
314.550 601.45	Presubmission of non-launch promotional materials for accelerated approval of products for serious or life-threatening illnesses	1	1.15.1.4	Presubmission of non-launch promotional materials for accelerated approval products
314.640	Presubmission of non-launch	1	1.15.1.4	Presubmission of non-launch promotional

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
601.94	promotional materials for products approved when human efficacy studies are not ethical or feasible			materials for accelerated approval products
202.1 Section 503C of the Food, Drug, and Cosmetic Act	Pre-dissemination review of television ads	1	1.15.1.5	Pre-dissemination review of television ads
202.1	Response to untitled letter or warning letter	1	1.15.1.6	Response to untitled letter or warning letter
202.1	Response to information request	1	1.15.1.7	Response to information request
202.1 314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94	Correspondence accompanying materials previously missing or rejected	1	1.15.1.8	Correspondence accompanying materials previously missing or rejected
202.1 314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94	Withdrawal request	1	1.15.1.9	Withdrawal request
202.1 202.1(j)(4) 314.550 601.45	Submission of annotated references	1	1.15.1.10	Submission of annotated references

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.640 601.94				
202.1	General correspondence	1	1.15.1.11	General correspondence
314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Regulations related to promotional materials [use appropriate sections]	1	1.15.2	Materials ** [promotional-material-doc-type]
314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Regulations related to promotional materials [use appropriate sections]	1	1.15.2.1	Material **[promotional-material-type, material-id, issue-date]
202.1 314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94	Clean version	1	1.15.2.1.1	Clean version
202.1(j)(4) 314.550 601.45 314.640	Annotated version	1	1.15.2.1.2	Annotated version

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
601.94 202.1				
202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Annotated labeling version	1	1.15.2.1.3	Annotated labeling version
202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Annotated references	1	1.15.2.1.4	Annotated references
FDAAA 505-1 [355-1]	Risk evaluation and mitigation strategies (REMS)	1	1.16	Use the appropriate sections
FDAAA	Correspondence regarding postmarketing commitments	1	1.17.1	Correspondence regarding postmarketing commitments
FDAAA	Correspondence regarding postmarketing requirements	1	1.17.2	Correspondence regarding postmarketing requirements
	Proprietary names	1	1.18	Proprietary names
314.50(d)(5)(viii)	An integrated summary of the benefits and risks	2	2.5	Use appropriate sections
314.50(c)(2)(ii) to (ix)	Summaries…	2	As needed	Use the appropriate sections
314.50(d)(7)	Pediatric use section	2 and 5	As needed	Use appropriate sections
314.50(d)(1)(i) and (ii)	Chemistry, manufacturing and controls	3	As needed	Use the appropriate sections
314.50(e)(2)(i)	Analytical methods	3	As needed	Use appropriate sections

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.60	Amendment to an unapproved application: Chemistry	3	As needed	Use appropriate sections
600.81	Distribution reports	3	3.2.R	Regional Information
314.81(b)(2)(iv)	Annual Report: Chemistry, manufacturing, and controls	3	As needed	Use appropriate sections
314.50(d)(2)	Nonclinical pharmacological and toxicology section	4	As needed	Use appropriate sections
314.81(b)(2)(v)	Annual Report: Nonclinical laboratory studies	4	As needed	Use appropriate sections
314.60	Amendment to an unapproved application: Toxicology	4	As needed	Use appropriate sections
314.50(d)(5)(ix)	Statement of compliance with informed consent	5	5.3	*List of IECs or IRBs and consent forms [under specific study]
314.50(d)(5)(xi)	Audited studies	5	5.3	*Audit certificates and reports [under specific study]
314.50(d)(6)(i) and (ii)	Description of statistical analysis	5	5.3	*Documentation of statistical methods and interim analysis plans [under specific study]
314.50(f)(1)	Case report tabulations	5	5.3	*Case report tabulations [use the appropriate sections under the specific study]
314.50(f)(2)	Case report forms	5	5.3	*Case report forms [under the appropriate site and specific study]
314.50(d)(5)(i) to (iv)	Clinical data section	5	5.3	Use appropriate sections
314.50(d)(3)	Human pharmacokinetics and bioavailability sections	5	5.3	Use appropriate sections
314.50(d)(5)(vii)	Potential for abuse	5	5.3	Use appropriate sections
314.50(d)(5)(v)	An integrated summary of efficacy	5	5.3.4	Reports of analysis of data from more than one study [Use appropriate sections in integrated summary of efficacy STF]
314.50(d)(5)(vi)(a)	An integrated summary of safety	5	5.3.4	Reports of analysis of data from more than one study [Use appropriate sections in integrated summary of safety STF]

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.50(d)(5)(vi)(b)	Safety Update	5	5.3.5	Reports of analysis of data from more than one study [Use appropriate sections in integrated summary of safety STF]
314.50(d)(4)	Microbiology	5	5.3.5.4	Other study reports and related information [Use appropriate sections in microbiology STF]
314.80(c)(2)(ii)(a) 314.80(c)(2)(ii)(c) 600.80(c)(20(ii)(A) 600.80(c)(2)(ii)(C)	Periodic adverse drug experience – narrative summary and history of actions	5	5.3.6	Postmarketing periodic adverse event drug experience report description
314.70 and 314.71 601.12	Supplements and other changes to approved applications	1, 2, 3, 4, 5	As needed	Use the appropriate sections
314.420(a)	Drug master files	1, 2, 3, 4, 5	As needed	Use appropriate sections
314.60	Amendment to an unapproved application: Clinical	5	As needed	Use appropriate sections
314.81(b)(2)(vi)	Annual Report: Clinical data	5	As needed	Use appropriate sections
315.50(b)	Index	N/A	N/A	N/A

ANDA

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.94(a)(1)	Application Form FDA 356h	1	1.1	**Forms form-type=356h
GDUFA	Form FDA 3794: Generic Drug User Fee Cover Sheet	1	1.1	**Forms form-type=3794
FDAAA	Certification of compliance: Form FDA 3674	1	1.1	**Forms form-type=3674
	Transmittal of labels and circulars: Form FDA 2567	1	1.1	**Forms form-type=2567
314.81(b)(3)(i)	Transmittal of advertisements and promotional labeling: Form FDA 2253	1	1.1	**Forms form-type=2253
	Cover letters	1	1.2	Cover letters
	Change of address or corporate name NOTE: Includes DMF original address or corporate name or change in DMF address or corporate name	1	1.3.1.1	Change of address or corporate name
	Change in contact/agent NOTE: Includes DMF original contact/agent or change in DMF contact/agent	1	1.3.1.2	Change in contact/agent
314.72	Change in ownership of an application	1	1.3.1.5	Change in ownership of an application
314.50(d)(1)(v)	Field copy certification	1	1.3.2	Field copy certification
Generic Drug Enforcement Act (GDEA)	Debarment certification	1	1.3.3	Debarment certification
314.94(13)	Financial certification and disclosure (Form FDA 3454 and Form FDA 3455)	1	1.3.4	Financial certification and disclosure

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.50(h) 314.53(e)	Patent information (Form FDA 3542a and Form FDA 3542)	1	1.3.5.1	Patent information
314.94(12)	Patent certification	1	1.3.5.2	Patent certification
314.95	Notice of certification of nonvalidity or noninfringement of patent	1	1.3.5.3	Exclusivity claim
314.420(d)	Incorporating DMF information by reference (authorization from DMF holder)	1	1.4.1	Letter of authorization
314.50(g)(1)	Written statement of authorization for references (copy of LOA received from DMF holders - submitted by BLA, NDA, or IND applicants)	1	1.4.2	Statement of right of reference
314.420(d)	List of authorized persons to incorporate by reference	1	1.4.3	List of authorized persons to incorporate by reference
314.94(11)	Reference to information previously submitted	1	1.4.4	Cross-reference to previously submitted information
314.65	Withdrawal of an unapproved application	1	1.5.5	Withdrawal of an unapproved BLA, NDA, ANDA or Supplement
314.150	Withdrawal of listed drug	1	1.5.6	Withdrawal of listed drug
314.150(c)	Request for withdrawal of approval	1	1.5.7	Withdrawal of approval of an application or revocation of license
314.102	Communications: meetings	1	1.6.1	Meeting request
314.102	Communications: meetings	1	1.6.2	Meeting background materials
314.102	Communications: meetings	1	1.6.3	Correspondence regarding meetings
314.103(c)	Scientific and medical disputes	1	1.10.1	Request for dispute resolution
314.103(c)	Scientific and medical disputes	1	1.10.2	Correspondence related to dispute resolution
314.96	Amendment to an unapproved application: Chemistry	1	1.11.1	Quality information amendment

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
	(information not fitting under Module 3)			
314.98	Amendment to an unapproved application: Toxicology (information not covered under Module 4)	1	1.11.2	Nonclinical information amendment
314.96	Amendment to an unapproved application: Clinical (information not fitting under Module 5)	1	1.11.3	Clinical information amendment
314.96	Multiple information amendment:	1	1.11.4	Multiple module information amendment
	Request for comment and advice	1	1.12.4	Request for comments and advice
GDEA	Generic drug enforcement act statement	1	1.12.10	Generic drug enforcement act statement
314.94(a)(3)	Basis for abbreviated new drug application submission	1	1.12.11	ANDA basis for submission statement
314.94(a)(4)	Conditions for use	1	1.12.11	ANDA basis for submission statement
314.94(a)(5)	Active ingredient	1	1.12.12	Comparison of generic drug and reference listed drug
314.94(a)(6)	Route of administration, dosage form, and strength	1	1.12.12	Comparison of generic drug and reference listed drug
25.15(d)	Environmental impact analysis statement (if applicable)	1	1.12.14	Environmental analysis
320.22 (a)	Request for waiver of in vivo bioavailability studies	1	1.12.15	Request for waiver of in-vivo bioavailability studies
314.81(b)(i)(ii)	Field alert reports	1	1.12.16	Field alert reports
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.1	Summary of nonclinical studies
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.2	Summary of clinical pharmacology information
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.3	Summary of safety information

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.4	Summary of labeling changes
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.5	Summary of manufacturing changes
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.6	Summary of microbiological changes
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.7	Summary of other significant new information
314.81(b)(2)(ii)	Annual Report: Distribution data	1	1.13.11	Distribution data
314.81(b)(2)(vii)	Annual Report: Status report of clinical and nonclinical toxicology postmarketing study commitments	1	1.13.12	Status of postmarketing study commitments and requirements
314.81(b)(2)(viii)	Status report of other (chemistry, manufacturing, controls) postmarketing study commitments	1	1.13.13	Status of other postmarketing studies and requirements
314.81(b)(2)(ix)	Annual Report: Log of outstanding regulatory business	1	1.13.14	Log of outstanding regulatory business
314.94(a)(8)(ii)	Copies of proposed labeling [Use appropriate sections]	1	1.14.1	Draft labeling
314. 94(a)(8)(ii)	Draft carton and container labels	1	1.14.1.1	Draft carton and container labels
314.50(c)(2)(i)	The proposed text of the labeling with annotations	1	1.14.1.2	Annotated draft labeling text
314.94(a)(8)(ii)	Draft labeling text	1	1.14.1.3	Draft labeling text
314.94(a)(8)(ii)	Final carton or container labels	1	1.14.2.1	Final carton or container labels
314.94(a)(8)(ii)	Final package insert (package inserts, patient information, medication guides)	1	1.14.2.2	Final package insert (package inserts, patient information, medication guides)
314.94(a)(8)(ii)	Final labeling text	1	1.14.2.3	Final labeling text
314.94(a)(8)(iii)	Statement of proposed labeling	1	1.14.3.1	Annotated comparison with listed drug
314.94(a)(8)(iv)	Comparison of approved and proposed labeling	1	1.14.3.1	Annotated comparison with listed drug
314.94(a)(8)(i)	Listed drug labeling	1	1.14.3.2	Approved labeling text for listed drug

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.94(a)(8)(i)	Labeling text for reference listed drug	1	1.14.3.3	Labeling text for reference listed drug
314.81(b)(3)(i)	Product labeling for 2253 submissions (if applicable)	1	1.14.6	Product labeling for 2253 submissions
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Regulations related to promotional materials [use appropriate sections]	1	1.15	Promotional material **[attribute = promotional-material-audience-type]
202.1 202.1(j)(4)	Request for advisory comments on launch materials	1	1.15.1.1	Request for advisory comments on launch materials
202.1 202.1(j)(4)	Request for advisory comments on non-launch materials	1	1.15.1.2	Request for advisory comments on non-launch materials
202.1 314.550	Presubmission of launch promotional materials for accelerated approval products	1	1.15.1.3	Presubmission of launch promotional materials for accelerated approval products
202.1 314.640	Presubmission of launch promotional materials for products approved when human efficacy studies are not ethical or feasible	1	1.15.1.3	Presubmission of launch promotional materials for accelerated approval products
202.1 314.550	Presubmission of non-launch promotional materials for accelerated approval products	1	1.15.1.4	Presubmission of non-launch promotional materials for accelerated approval products
314.640	Presubmission of non-launch promotional materials for products approved when human efficacy studies are not ethical or feasible	1	1.15.1.4	Presubmission of non-launch promotional materials for accelerated approval products

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
202.1 Section 503C of the Federal Food, Drug, and Cosmetic Act	Pre-dissemination review of television ads	1	1.15.1.5	Pre-dissemination review of television ads
202.1	Response to untitled letter or warning letter	1	1.15.1.6	Response to untitled letter or warning letter
202.1	Response to information request	1	1.15.1.7	Response to information request
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Correspondence accompanying materials previously missing or rejected	1	1.15.1.8	Correspondence accompanying materials previously missing or rejected
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Withdrawal request	1	1.15.1.9	Withdrawal request
202.1 202.1(j)(4) 314.550 314.640	Submission of annotated references	1	1.15.1.10	Submission of annotated references
202.1	General correspondence	1	1.15.1.11	General correspondence
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Regulations related to submission of promotional materials [use appropriate sections]	1	1.15.2	Materials **[attribute = promotional-material-doc-type]
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550	Regulations related to promotional materials [use appropriate sections]	1	1.15.2.1	Material **[attributes =promotional-material-type, material-id, issue-date]

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
314.640				
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Clean version	1	1.15.2.1.1	Clean version
202.1 202.1(j)(4) 314.550 314.640	Annotated version	1	1.15.2.1.2	Annotated version
202.1 202.1(j)(4) 314.550 314.640	Annotated labeling version	1	1.15.2.1.3	Annotated labeling version
202.1 202.1(j)(4) 314.550 314.640	Annotated references	1	1.15.2.1.4	Annotated references
FDAAA 505-1 [355-1]	Risk evaluation and mitigation strategies (REMS)	1	1.16	Use the appropriate sections
FDAAA	Correspondence regarding postmarketing commitments	1	1.17.1	Correspondence regarding postmarketing commitments
FDAAA	Correspondence regarding postmarketing requirements	1	1.17.2	Correspondence regarding postmarketing requirements
314.420(a)	Drug master files	1, 2, 3, 4, 5	As needed	Use appropriate sections
314.96	Amendment to an unapproved application: Chemistry	3	As needed	Use appropriate sections
314.94(9)	Chemistry, manufacturing, and control	3	As needed	Use appropriate sections
314.94(a)(7)	Bioequivalence	5	5.3	Use appropriate sections
314.96	Amendment to an unapproved	5	As needed	Use appropriate sections

CFR Citation/Source		CTD /*STF Heading/**Attribute(s)		
NUMBER	**TITLE**	**MODULE**	**NUMBER**	**TITLE**
	application: Clinical			
314.94(a)(2)	Table of Contents	N/A	N/A	N/A

Appendix 2 – Module 1 Summary of Changes

A. Module 1 Summary of Changes (02/07/2014, version 2.3)

Module Section	Old Title	New Title
1.15.1.5	Promotional materials submitted pursuant to section 503B	Pre-dissemination review of television ads

B. Module 1 Summary of Changes (08/23/2013, version 2.2)

Module Section	Old Title	New Title
1.15.2.1	Material <attribute = [promotional-material-type]>	1.15.2.1 Material [attributes=promotional-material-type, material-id, issue-date]

C. Module 1 Summary of Changes (11/1/2012, version 2.1)

Module Section	Old Title	New Title
1.16	Risk evaluation and mitigation strategies (REMS)	Risk Management Plan
1.16.1	N/A	Risk Management (Non-REMS)
1.16.2	N/A	Risk Evaluation and Mitigation Strategy (REMS)
1.16.2.1	N/A	Final REMS
1.16.2.2	N/A	Draft REMS
1.16.2.3	N/A	REMS Assessment
1.16.2.4	N/A	REMS Assessment Methodology
1.16.2.5	N/A	REMS Correspondence
1.16.2.6	N/A	REMS Modification History

D. **Module 1 Summary of Changes (6/1/2012, version 2.0)**

Module Section	Old Title	New Title
1.1	Forms and form type e.g. 1.1.1 Application form: FDA form 1571 1.1.2 Application form: FDA form 356h 1.1.3 User fee cover sheet: FDA form 3397 1.1.4 Annual report transmittal: FDA form 2252 1.1.5 Advertisements and promotional labeling transmittal: FDA form 2253 1.1.6 Transmittal of Labels and Circulars: FDA form 2567	Forms Form ** [attribute = form-type]
1.3.1.5	Change in ownership of an application	Change in ownership of an application or reissuance of license
1.3.5.3	Exclusivity request	Exclusivity claim
1.3.6	N/A	Tropical disease priority review voucher
1.4.4	Cross reference to other applications	Cross-reference to previously submitted information
1.5.1	Withdrawal request	Withdrawal of an IND
1.5.5	Withdrawal of an unapproved NDA	Withdrawal of an unapproved BLA, NDA, ANDA, or supplement
1.5.7	Request for withdrawal of application approval	Withdrawal of approval of an application or revocation of license
1.7.4	N/A	Correspondence regarding fast track/rolling review
1.8.4.	N/A	Animal efficacy study for approval under the animal rule
1.9.5	Proposal for written agreement	No longer applicable
1.11.2	Safety information amendment	Nonclinical information amendment
1.11.3	Efficacy information amendment	Clinical information amendment
1.11.4	N/A	Multiple module information amendment
1.12.2	Request to charge	Request to charge for clinical trial
1.12.3	Notification of charging under treatment IND	Request to charge for expanded access

Module Section	Old Title	New Title
1.12.6	Exception from informed consent for research	Exception from informed consent for emergency research
1.12.7	Public disclosure statement for exception from informed consent for research	Public disclosure statement for exception from informed consent for emergency research
1.12.8	Correspondence regarding exception from informed consent for research	Correspondence regarding exception from informed consent for emergency research
1.12.11	Basis for submission statement	ANDA basis for submission statement
1.12.17	N/A	Orphan drug designation
1.13.12	Status of postmarketing study commitments	Status of postmarketing study commitments and requirements
1.13.13	Status of other postmarketing studies	Status of other postmarketing studies and requirements
1.13.15	N/A	Development safety update report (DSUR)
1.14.6	N/A	Product labeling for 2253 submissions
1.15	Promotional material	Promotional material <attribute = [promotional-material-audience-type]>
1.15.1	N/A	Correspondence relating to promotional materials
1.15.1.1	N/A	Request for advisory comments on launch materials
1.15.1.2	N/A	Request for advisory comments on non-launch materials
1.15.1.3	N/A	Presubmission of launch promotional materials for accelerated approval products
1.15.1.4	N/A	Presubmission of non-launch promotional materials for accelerated approval products
1.15.1.5	N/A	Promotional materials submitted pursuant to section 503B
1.15.1.6	N/A	Response to untitled letter or warning letter
1.15.1.7	N/A	Response to information request
1.15.1.8	N/A	Correspondence accompanying materials previously missing or rejected
1.15.1.9	N/A	Withdrawal request
1.15.1.10	N/A	Submission of annotated references
1.15.1.11	N/A	General correspondence
1.15.2	N/A	Materials <attribute = [promotional-material-doc-type]>

Module Section	Old Title	New Title
1.15.2.1	N/A	Material <attribute = [promotional-material-type]>
1.15.2.1.1	N/A	Clean version
1.15.2.1.2	N/A	Annotated version
1.15.2.1.3	N/A	Annotated labeling version
1.15.2.1.4	N/A	Annotated references
1.16	Risk management plans	Risk evaluation and mitigation strategies (REMS)
1.17	N/A	Postmarketing studies
1.17.1	N/A	Correspondence regarding postmarketing commitments
1.17.2	N/A	Correspondence regarding postmarketing requirements
1.18	N/A	Proprietary names
1.19	N/A	Pre-EUA and EUA
1.20	N/A	General investigational plan for initial IND