

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
2020-11-09	2.3.3	Added file tags under sections 4.2.1.1, 5.3.1.1, and 5.3.5.4 to align with file tags in ICH valid values version 5.0.
2024-09-09	2.3.4	Added file tags under sections 4.2.1.1, 5.3.1.1, and 5.3.5.3 to align with file tags in ICH valid values version 6.0 (<i>support date TBD</i>).

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1.3.5.1 Patent information

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1.3.5.3 Exclusivity claim

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1.4 References

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1.5.3 Reactivation request

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1.6.3 Correspondence regarding meetings

1.7 Fast track

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1.7.3 Rolling review request

1.7.4 Correspondence regarding fast track/rolling review

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1.11 Information amendment: Information not covered under modules 2 to 5

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 - 1.14.1.3 Draft labeling text**
 - 1.14.1.4 Label comprehension studies**
 - 1.14.1.5 Labeling history**
- 1.14.2 Final labeling
 - 1.14.2.1 Final carton or container labels**
 - 1.14.2.2 Final package insert (package inserts, patient information, medication guides)**
 - 1.14.2.3 Final labeling text**
- 1.14.3 Listed drug labeling
 - 1.14.3.1 Annotated comparison with listed drug**
 - 1.14.3.2 Approved labeling text for listed drug**
 - 1.14.3.3 Labeling text for reference listed drug**
- 1.14.4 Investigational drug labeling
 - 1.14.4.1 Investigational brochure**
 - 1.14.4.2 Investigational drug labeling**
- 1.14.5 Foreign labeling
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1.15 Promotional material [promotional-material-audience-type]

- 1.15.1 Correspondence relating to promotional materials
 - 1.15.1.1 Request for advisory comments on launch materials**
 - 1.15.1.2 Request for advisory comments on non-launch materials**
 - 1.15.1.3 Presubmission of launch promotional materials for accelerated approval products**
 - 1.15.1.4 Presubmission of non-launch promotional materials for accelerated approval products**
 - 1.15.1.5 Pre-dissemination review of television ads**
 - 1.15.1.6 Response to untitled letter or warning letter**
 - 1.15.1.7 Response to information request**
 - 1.15.1.8 Correspondence accompanying materials previously missing or rejected**
 - 1.15.1.9 Withdrawal request**

- 1.15.1.10 **Submission of annotated references**
 - 1.15.1.11 **General correspondence**
 - 1.15.2 Materials attribute = [promotional-material-doc-type]
 - 1.15.2.1 **Material [promotional-material-type, material-id, issue- date]**
 - 1.15.2.1.1 Clean version
 - 1.15.2.1.2 Annotated version
 - 1.15.2.1.3 Annotated labeling version
 - 1.15.2.1.4 Annotated references
 - 1.16 Risk management plan**
 - 1.16.1 Risk Management (Non-REMS)
 - 1.16.2 Risk Evaluation and Mitigation Strategy (REMS)
 - 1.16.2.1 **Final REMS**
 - 1.16.2.2 **Draft REMS**
 - 1.16.2.3 **REMS Assessment**
 - 1.16.2.4 **REMS Assessment Methodology**
 - 1.16.2.5 **REMS Correspondence**
 - 1.16.2.6 **REMS Modification History**
 - 1.17 Postmarketing studies**
 - 1.17.1 Correspondence regarding postmarketing commitments
 - 1.17.2 Correspondence regarding postmarketing requirements
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 - 1.19 Pre-EUA and EUA**
 - 1.20 General investigational plan for initial IND**

Module 2 Summaries

- 2.2 Introduction to summary**
- 2.3 Quality overall summary**
- 2.4 Nonclinical overview**
- 2.5 Clinical overview**
- 2.6 Nonclinical written and tabulated summaries**
 - 2.6.1 Introduction
 - 2.6.2 Pharmacology written summary
 - 2.6.3 Pharmacology tabulated summary
 - 2.6.4 Pharmacokinetic written summary
 - 2.6.5 Pharmacokinetic tabulated summary
 - 2.6.6 Toxicology written summary
 - 2.6.7 Toxicology tabulated summary
- 2.7 Clinical summary**
 - 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods
 - 2.7.2 Summary of Clinical Pharmacology studies
 - 2.7.3 Summary of Clinical Efficacy [indication]
 - 2.7.4 Summary of Clinical Safety
 - 2.7.5 References
 - 2.7.6 Synopses of individual studies

Module 3 Quality

3.2 Body of data

- 3.2.S Drug substance [name, manufacturer]
 - 3.2.S.1 General information**
 - 3.2.S.1.1 Nomenclature
 - 3.2.S.1.2 Structure
 - 3.2.S.1.3 General properties
 - 3.2.S.2 Manufacture**
 - 3.2.S.2.1 Manufacturer(s)
 - 3.2.S.2.2 Description of Manufacturing Process and Process Controls
 - 3.2.S.2.3 Control of Materials
 - 3.2.S.2.4 Controls of Critical Steps and Intermediates
 - 3.2.S.2.5 Process Validation and/or Evaluation
 - 3.2.S.2.6 Manufacturing Process Development
 - 3.2.S.3 Characterization**
 - 3.2.S.3.1 Elucidation of Structure and other Characteristics
 - 3.2.S.3.2 Impurities
 - 3.2.S.4 Control of drug substance**
 - 3.2.S.4.1 Specification
 - 3.2.S.4.2 Analytical Procedures
 - 3.2.S.4.3 Validation of Analytical Procedures
 - 3.2.S.4.4 Batch Analyses
 - 3.2.S.4.5 Justification of Specification
 - 3.2.S.5 Reference standards or materials**
 - 3.2.S.6 Container closure systems**
 - 3.2.S.7 Stability**
 - 3.2.S.7.1 Stability Summary and Conclusions
 - 3.2.S.7.2 Post Approval Stability Protocol and Stability Commitment
 - 3.2.S.7.3 Stability Data
- 3.2.P Drug product [name, dosage form, manufacturer]
 - 3.2.P.1 Description and composition of the drug product**
 - 3.2.P.2 Pharmaceutical development**
 - 3.2.P.3 Manufacture**
 - 3.2.P.3.1 Manufacturer(s)
 - 3.2.P.3.2 Batch Formula
 - 3.2.P.3.3 Description of Manufacturing Process and Process Controls
 - 3.2.P.3.4 Controls of Critical Steps and Intermediates
 - 3.2.P.3.5 Process Validation and/or Evaluation
 - 3.2.P.4 Control of excipients [name]**
 - 3.2.P.4.1 Specification(s)
 - 3.2.P.4.2 Analytical Procedures
 - 3.2.P.4.3 Validation of Analytical Procedures
 - 3.2.P.4.4 Justification of Specifications
 - 3.2.P.4.5 Excipients of Human or Animal Origin
 - 3.2.P.4.6 Novel Excipients
 - 3.2.P.5 Control of drug product**
 - 3.2.P.5.1 Specification(s)
 - 3.2.P.5.2 Analytical Procedures
 - 3.2.P.5.3 Validation of Analytical Procedures

- 3.2.P.5.4 Batch Analyses
- 3.2.P.5.5 Characterization of Impurities
- 3.2.P.5.6 Justification of Specification(s)

3.2.P.6 Reference standards or materials

3.2.P.7 Container closure system

3.2.P.8 Stability

- 3.2.P.8.1 Stability Summary and Conclusion
- 3.2.P.8.2 Postapproval Stability Protocol and Stability Commitment
- 3.2.P.8.3 Stability Data

3.2.A Appendices

3.2.A.1 Facilities and Equipment [name, manufacturer]

3.2.A.2 Adventitious agents safety evaluation [name, dosage form, manufacturer]

3.2.A.3 Novel excipients

3.2.R Regional information

3.3 Literature references

Module 4 Nonclinical Study Reports

4.2 Study reports

4.2.1 Pharmacology

4.2.1.1 Primary pharmacodynamics

Study report [identification number] and related information

Legacy clinical study report

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

Assay validation

Biomarkers

Data monitoring review committees
Device information
Diagnostic tests
Gene therapy
Pharmacodynamics
Pharmacogenomics
Pharmacokinetics
Stem cells
Antibody
Other data not specified
PK PD relationship
Specialty report
Foreign clinical studies not under ind
PD InVivo Study (TBD)
PD InVitro Study (TBD)
QT InVitro Study (TBD)
Study data reviewer's guide (TBD)
Weight of evidence (TBD)
Animal rule efficacy (TBD)
Animal rule natural history (TBD)
nonstandard safety study (TBD)

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

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.2.5 Excretion

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.2.6 Pharmacokinetic drug interactions

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for heading

4.2.2.7 Other pharmacokinetic studies

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3 Toxicology

4.2.3.1 Single dose toxicity [Species and route]

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3.2 Repeat dose toxicity [Species, route, duration]

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3.3 Genotoxicity

4.2.3.3.1 In vitro

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3.3.2 In vivo

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3.4 Carcinogenicity

4.2.3.4.1 Long term studies [Species]

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3.4.2 Short or medium term studies

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3.4.3 Other studies

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3.5 Reproductive and developmental toxicity

4.2.3.5.1 Fertility and early embryonic development

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

4.2.3.5.2 Embryofetal development

Study report [identification number] and related information
See Primary pharmacodynamics Study report and related information for headings

information for headings

4.2.3.5.3 Prenatal and postnatal development, including maternal function

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.5.4 Studies in which the offspring (juvenile animals) are dosed and/or further evaluated

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.6 Local tolerance

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.7 Other toxicity studies

4.2.3.7.1 Antigenicity

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.7.2 Immunotoxicity

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.7.3 Mechanistic studies

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.7.4 Dependence

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.7.5 Metabolites

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.7.6 Impurities

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.2.3.7.7 Other

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for headings

4.3 Literature references

Module 5 Clinical Study Reports

5.2 Tabular listing of all clinical studies

5.3 Clinical study reports and related information

5.3.1 Reports of biopharmaceutic studies

5.3.1.1 Bioavailability (BA) Study reports and related information

Study report [identification] and related information

Legacy clinical study report

Synopsis (ICH E3, section 2)

Study report body (E3 1, 3 to 15)

Protocol or amendment (E3 16.1.1)

Sample case report form (E3 16.1.2)

IEC-IRB consent form list (E3 16.1.3)

List description investigator site (E3 16.1.4)

Signatures investigators (E3 16.1.5)

List patients with batches (E3 16.1.6)

Randomisation scheme (E3 16.1.7)

Audit certificates report (E3 16.1.8)

Statistical methods interim analysis plan (E3 16.1.9)

Inter-laboratory standardisation methods quality assurance (E3 16.1.10)

Publications based on study (E3 16.1.11)

Publications referenced in report (E3 16.1.12)

Discontinued patients (E3 16.2.1)

Protocol deviations (E3 16.2.2)

Patients excluded from efficacy analysis (E3 16.2.3)

Demographic data (E3 16.2.4)

Compliance and drug concentration data (E3 16.2.5)

Individual efficacy response data (E3 16.2.6)

Adverse event listings (E3 16.2.7)

Listing individual laboratory measurements by patient (E3 16.2.8)

Case report forms (E3 16.3)

Site [identifier]

CSR Other (TBD)

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

Assay validation

Biomarkers

Data monitoring review committees
Device information
Diagnostic tests
Gene therapy
Patient reported outcomes
Pharmacodynamics
Pharmacogenomics
Pharmacokinetics
Quality of life
Hepatic Impairment Study (TBD)
Renal Impairment Study (TBD)
Drug-drug Interaction Study (TBD)
Mass Balance Study (TBD)
Population PK Report (TBD)
Population PKPD Report (TBD)
PBPK Report (TBD)
PBBM Report (TBD)
QSP Report (TBD)
CP General (TBD)
QT Clinical Study (TBD)
Stem cells
Abuse liability
Antibody
Healthcare utilization
Other data not specified
PK/PD relationship
Specialty report
Foreign clinical studies not under ind
Study data reviewer's guide (TBD)
Analysis data reviewer's guide (TBD)

5.3.1.2 Comparative BA and bioequivalence (BE) Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.1.3 In Vitro - in Vivo correlation Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.1.4 Reports of bioanalytical and analytical methods for human studies

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.2 Reports of studies pertinent to pharmacokinetics using human biomaterials

5.3.2.1 Plasma protein binding Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.2.2 Reports of hepatic metabolism and drug interaction studies

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.2.3 Reports of studies using other human biomaterials

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.3 Reports of human pharmacokinetic (PK) studies

5.3.3.1 Healthy subject PK and initial tolerability Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.3.2 Patient PK and initial tolerability Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.3.3 Intrinsic factor PK Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.3.4 Extrinsic factor Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.3.5 Population PK Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.4 Reports of human pharmacodynamic (PD) studies

5.3.4.1 Healthy subject PD and PK/PD Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.4.2 Patient PD and PK/PD Study reports and related information

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.5 Reports of efficacy and safety studies [Indication]

5.3.5.1 Study reports and related information of controlled clinical studies pertinent to the claimed indication [type of control]

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.5.2 Study reports and related information of uncontrolled clinical studies

Study report [identification] and related information

See example under bioavailability (BA) Study reports and related information for headings

5.3.5.3 Reports of analyses of data from more than one study

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

Integrated analysis of clinical pharmacology

iscp (TBD)

Analysis datasets

Analysis dataset adam

Analysis dataset legacy

Analysis program

Analysis data definition

Integrated analysis of immunogenicity

isi (TBD)

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

Antibacterial microbiology reports

Antibacterial

Special pathogens (e.g., fungi, parasites, mycobacteria) and immune modulator reports

Special pathogen

Antiviral reports

Antiviral

BIMO

bimo

Human Factor

HF validation protocol

HF validation report

HF validation other

5.3.6 Reports of postmarketing experience

Postmarketing periodic adverse event drug experience report
description

5.4 Literature references

Appendix 1 – 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

IND Mapping Section

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

IND Mapping Section

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

IND Mapping Section

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

IND Mapping Section

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

IND Mapping Section

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]

IND Mapping Section

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

NDA and BLA Mapping Section

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

NDA and BLA Mapping Section

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

NDA and BLA Mapping Section

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

NDA and BLA Mapping Section

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

NDA and BLA Mapping Section

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

NDA and BLA Mapping Section

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

NDA and BLA Mapping Section

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

NDA and BLA Mapping Section

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

NDA and BLA Mapping Section

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	5.3.5.3	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	5.3.5.3	Reports of analysis of data from more than one study [Use appropriate sections in integrated summary of safety STF]

NDA and BLA Mapping Section

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 Mapping Section

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

ANDA Mapping Section

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

ANDA Mapping Section

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

ANDA Mapping Section

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

ANDA Mapping Section

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

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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]

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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

ANDA Mapping Section

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