

The Comprehensive Table of Contents Headings and Hierarchy
Draft — Not for Implementation

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
2011-08-01	2.0	Corrections and additions to the mapping tables based on major update to Module 1 specifications (Summary in Appendix 2)

Table of Contents

MODULE 1 ADMINISTRATIVE INFORMATION	1
MODULE 2 SUMMARIES	4
MODULE 3 QUALITY	4
MODULE 4 NONCLINICAL STUDY REPORTS	6
MODULE 5 CLINICAL STUDY REPORTS	9
APPENDIX 1 - MAPPING	13
IND	13
NDA AND BLA	20
ANDA.....	29
APPENDIX 2 - MODULE 1 SUMMARY OF CHANGES (VERSION 2.0)	35

The Comprehensive Table of Contents Headings and Hierarchy

Module 1 Administrative information

1.1 Forms

Form <attribute = [form-type]>

1.2 Cover letters

1.3 Administrative information

1.3.1 Contact/sponsor/applicant information

1.3.1.1 Change of address or corporate name

1.3.1.2 Change in contact/agent

1.3.1.3 Change in sponsor

1.3.1.4 Transfer of obligation

1.3.1.5 Change in ownership of an application

1.3.2 Field copy certification

1.3.3 Debarment certification

1.3.4 Financial certification and disclosure

1.3.5 Patent and exclusivity

1.3.5.1 Patent information

1.3.5.2 Patent certification

1.3.5.3 Exclusivity claim

1.3.6 Tropical disease priority review voucher

1.4 References

1.4.1 Letter of authorization

1.4.2 Statement of right of reference

1.4.3 List of authorized persons to incorporate by reference

1.4.4 Cross-reference to previously submitted information

1.5 Application status

1.5.1 Withdrawal of an IND

1.5.2 Inactivation request

1.5.3 Reactivation request

1.5.4 Reinstatement request

1.5.5 Withdrawal of an unapproved BLA, NDA, ANDA, or Supplement

1.5.6 Withdrawal of listed drug

1.5.7 Request for withdrawal of application approval

1.6 Meetings

1.6.1 Meeting request

1.6.2 Meeting background materials

1.6.3 Correspondence regarding meetings

1.7 Fast track

1.7.1 Fast track designation request

1.7.2 Fast track designation withdrawal request

1.7.3 Rolling review request

1.7.4 Correspondence regarding fast track/rolling review

1.8 Special protocol assessment request

- 1.8.1 Clinical study
- 1.8.2 Carcinogenicity study
- 1.8.3 Stability study
- 1.8.4 Animal efficacy study for approval under the animal rule

1.9 Pediatric administrative information

- 1.9.1 Request for waiver of pediatric studies
- 1.9.2 Request for deferral of pediatric studies
- 1.9.3 Request for pediatric exclusivity determination
- 1.9.4 Proposed pediatric study request and amendments
- 1.9.5 Proposal for written agreement (**no longer applicable**)
- 1.9.6 Other correspondence regarding pediatric exclusivity or study plans

1.10 Dispute resolution

- 1.10.1 Request for dispute resolution
- 1.10.2 Correspondence related to dispute resolution

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

- 1.11.1 Quality information amendment
- 1.11.2 Safety information amendment
- 1.11.3 Efficacy information amendment
- 1.11.4 Multiple module information amendment

1.12 Other correspondence

- 1.12.1 Pre IND correspondence
- 1.12.2 Request to charge for clinical trial
- 1.12.3 Request to charge for expanded access
- 1.12.4 Request for comments and advice
- 1.12.5 Request for a waiver
- 1.12.6 Exception from informed consent for emergency research
- 1.12.7 Public disclosure statement for exception from informed consent for emergency research
- 1.12.8 Correspondence regarding exception from informed consent for emergency research
- 1.12.9 Notification of discontinuation of clinical trial
- 1.12.10 Generic drug enforcement act statement
- 1.12.11 ANDA basis for submission statement
- 1.12.12 Comparison of generic drug and reference listed drug
- 1.12.13 Request for waiver for in vivo studies
- 1.12.14 Environmental analysis
- 1.12.15 Request for waiver of in vivo bioavailability studies
- 1.12.16 Field alert reports
- 1.12.17 Orphan drug designation

1.13 Annual report

- 1.13.1 Summary for nonclinical studies
- 1.13.2 Summary of clinical pharmacology information
- 1.13.3 Summary of safety information
- 1.13.4 Summary of labeling changes
- 1.13.5 Summary of manufacturing changes

- 1.13.6 Summary of microbiological changes
- 1.13.7 Summary of other significant new information
- 1.13.8 Individual study information
- 1.13.9 General investigational plan
- 1.13.10 Foreign marketing
- 1.13.11 Distribution data
- 1.13.12 Status of postmarketing study commitments and requirements
- 1.13.13 Status of other postmarketing studies and requirements
- 1.13.14 Log of outstanding regulatory business
- 1.13.15 Development safety update report (DSUR)

1.14 Labeling

- 1.14.1 Draft labeling
 - 1.14.1.1 Draft carton and container labels**
 - 1.14.1.2 Annotated draft labeling text**
 - 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
- 1.14.6 Professional labeling and patient labeling that accompanies promotional labeling pieces

1.15 Promotional material <attribute = [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 Promotional materials submitted pursuant to section 503B**
 - 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 <attribute = promotional-material-type>
 - 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 evaluation and mitigation strategies (REMS)
- 1.17 Postmarketing studies
 - 1.17.1 Correspondence regarding postmarketing commitments
 - 1.17.2 Correspondence regarding postmarketing requirements
- 1.18 Proprietary names
- 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 study report

Synopsis

Study report body

Protocol and amendments

Signatures of principal or coordinating investigator(s)

Audit certifications and reports

Documentation of statistical methods and interim analysis plans

Documentation of inter laboratory standardization methods of quality assurance procedures if used

Publications based on the study

Important publications referenced in the report

Compliance and/or drug concentration data

Individual subject data listings

Data tabulation

Data tabulation datasets

Data definitions

Data listing datasets

Data listing datasets

Data definitions

Analysis datasets

Analysis datasets

Analysis programs

Data definitions

IND safety reports

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 Statement of QA differences

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

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 study report*
 - Synopsis (ICH E3, section 2)*
 - Study report (E3 1, 3 to 15)*
 - Protocol and amendments (E3 16.1.1)*
 - Sample case report form (E3 16.1.2)*
 - List of IECs or IRBs (E3 16.1.3) and consent forms*
 - List and description of investigators (E3 16.1.4) and sites*
 - Signatures of principal or coordinating investigator(s) or sponsor's responsible medical officer (E3 16.1.5)*
 - Listing of patients receiving test drug(s) from specified batch (E3 16.1.6)*
 - Randomisations scheme (E3 16.1.7)*
 - Audit certificates (E3 16.1.8) and reports*
 - Documentation of statistical methods (E3 16.1.9) and interim analysis plans*
 - Documentation of inter laboratory standardization methods of quality assurance procedures if used (E3 16.1.10)*
 - Publications based on the study (E3 16.1.11)*
 - Important publications referenced in the report (E3 16.1.12)*
 - Discontinued patients (E3 16.2.1)*
 - Protocol deviations (E3 16.2.2)*
 - Patients excluded from the efficacy analysis (E3 16.2.3)*
 - Demographic data (E3 16.2.4)*
 - Compliance and/or drug concentration data (E3 16.2.5)*
 - Individual efficacy response data (E3 16.2.6)*

Adverse event listings (E3 16.2.7)
Listing of individual laboratory measurements by patient (E3 16.2.8)
Case report forms (E3 16.3)
 Site [identifier]
Individual patient data listings (E3 16.4)
 Data tabulation
 Data tabulation datasets
 Data definitions
Data listing datasets
 Data listing datasets
 Data definitions
Analysis datasets
 Analysis datasets
 Analysis programs
 Data definitions
Annotated CRF
Annotated ECG waveform datasets
Image files
Subject profiles
IND safety reports

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

Integrated analysis of safety

Integrated summary of safety report

Analysis datasets

Analysis programs

Integrated analysis of efficacy

Integrated summary of efficacy report

Analysis datasets

Analysis programs

5.3.5.4 Other Study reports and related information

Antibacterial microbiology reports

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

Antiviral reports

5.3.6 Reports of postmarketing experience

Postmarketing periodic adverse event drug experience report description

5.4 Literature references

Appendix 1 - Mapping

IND

CFR Citation/Source		CTD /*STF Heading/** Attribute(s) Required		
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
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
312.23(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
312.23(b)	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

CFR Citation/Source		CTD /*STF Heading/** Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
312.45(d)	Request to resume clinical investigation under an inactive IND	1	1.5.3	Reactivation 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	Request for waiver of pediatric studies	1	1.9.1	Request for waiver of pediatric studies
PREA	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

CFR Citation/Source		CTD /*STF Heading/** Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
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(a)(1)	Information amendment: Chemistry - information not covered under Module 3	1	1.11.1	Quality information amendment
312.31(a)(1)	Information amendment: Toxicology - information not covered under Module 4	1	1.11.2	Safety information amendment
312.31(a)(1)	Information amendment: Clinical - information not covered under Module 5	1	1.11.3	Efficacy information amendment
312.31(a)(1)	Multiple Information amendment	1	1.11.4	Multiple module information amendment
	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
312.54	Exception from informed consent for research	1	1.12.6	Exception from informed consent for emergency research

CFR Citation/Source		CTD /*STF Heading/** Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
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) Required		
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)
201.100(d)(3)	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)(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
312.23(a)(3)(iv)	A brief description of the overall plan...	1	1.20	General investigational plan for initial IND
312.23(a)(3)(i)	Introductory statement	2	2.2	Introduction to summary

CFR Citation/Source		CTD /*STF Heading/** Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
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) Required		
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(c)	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(a)(1)	Information amendment: Toxicology	4	As needed	Use appropriate sections
312.31(a)(1)	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) Required		
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
314.81(b)(2)	Annual report transmittal: Form FDA 2252	1	1.1	**Forms form-type=2252
314.81(b)(3)(i) and 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 (a)	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
GDEA	Debarment certification	1	1.3.3	Debarment certification

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
314.50(k)	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 BLA, 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	Request for withdrawal of application approval
314.150(e) 601.43(a)	Withdrawal of approval by the FDA	1	1.5.7	Other correspondence regarding status of application or product

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
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
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	Request for waiver of pediatric studies	1	1.9.1	Request for waiver of pediatric studies
PREA	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

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
314.60	Amendment to an unapproved application: Toxicology (information not covered under Module 4)	1	1.11.2	Safety information amendment
314.60	Amendment to an unapproved application: Clinical (information not covered under Module 5)	1	1.11.3	Efficacy 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	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)	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
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

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
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
314.50(e)(2)(ii)	Copies of the labeling and all labeling for the drug product	1	1.14	Use appropriate sections
314.81(b)(2)(iii)	Annual Report: Labeling	1	1.14	Use appropriate sections
314.50	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
	Foreign labeling	1	1.14.5	Foreign labeling

CFR Citation/Source		CTD /*STF Heading/** Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
202.1	Professional labeling and patient labeling (if applicable) that accompanies promotional labeling pieces	1	1.14.6	Professional labeling and patient labeling that accompanies promotional labeling pieces
314.81(b)(3)(i) 601.12(f)(4)	Advertising and promotional labeling [use appropriate sections]	1	1.15	**Promotional material <attribute = [promotional-material-audience-type]>
314.550 601.45	Subpart H: Promotional materials	1	1.15	**Promotional material <attribute = [promotional-material-audience-type]>
314.640 601.94	Subpart I: Promotional materials [use appropriate sections]	1	1.15	**Promotional material <attribute = [promotional-material-audience-type]>
314.550 601.45	Subpart H: Promotional materials	1	1.15.1	Correspondence relating to promotional materials
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 and 601.45	Presubmission of launch promotional materials for accelerated approval products	1	1.15.1.3	Presubmission of launch promotional materials for accelerated approval products
314.550 and 601.45	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
Section 503B of the Food, Drug, and Cosmetic Act	Promotional materials submitted pursuant to section 503B	1	1.15.1.5	Promotional materials submitted pursuant to section 503B
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

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
202.1	Correspondence accompanying materials previously missing or rejected	1	1.15.1.8	Correspondence accompanying materials previously missing or rejected
202.1	Withdrawal request	1	1.15.1.9	Withdrawal request
202.1	Submission of annotated references	1	1.15.1.10	Submission of annotated references
202.1	General correspondence	1	1.15.1.11	General correspondence
314.550 601.45	Subpart H: Promotional materials	1	1.15.2	**Materials <attribute = [promotional-material-doc-type]>
314.550 601.45	Subpart H: Promotional materials	1	1.15.2.1	**Material <attribute = [promotional-material-type]>
202.1	Clean version	1	1.15.2.1.1	Clean version
202.1	Annotated version	1	1.15.2.1.2	Annotated version
202.1	Annotated labeling version	1	1.15.2.1.3	Annotated labeling version
202.1	Annotated references	1	1.15.2.1.4	Annotated references
FDAMA	Risk evaluation and mitigation strategies (REMS)	1	1.16	Risk evaluation and mitigation strategies (REMS)
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) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
314.60	Amendment to an unapproved application: Chemistry	3	As needed	Use appropriate sections
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) Required		
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	5.3.5.5	Other study reports and related information [Use appropriate sections in microbiology STF]
314.80©(2)(ii)(a) 314.80©(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) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
314.94(a)(1)	Application Form FDA 356h	1	1.1	**Forms form-type=356h
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
	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 (a)	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
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

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
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	Request for withdrawal of application approval
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 (information not fitting under Module 3)	1	1.11.1	Quality information amendment

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
314.98	Amendment to an unapproved application: Toxicology (information not covered under Module 4)	1	1.11.2	Safety information amendment
314.96	Amendment to an unapproved application: Clinical (information not fitting under Module 5)	1	1.11.3	Efficacy 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
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.4	Summary of labeling changes

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
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) Required		
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) 601.12(f)(4)	Advertising and promotional labeling [use appropriate sections]	1	1.15	**Promotional material <attribute = [promotional-material-audience-type]>
314.550 601.45	Subpart H: Promotional materials	1	1.15	**Promotional material <attribute = [promotional-material-audience-type]>
314.640 601.94	Subpart I: Promotional materials [use appropriate sections]	1	1.15	**Promotional material <attribute = [promotional-material-audience-type]>
314.550 601.45	Subpart H: Promotional materials	1	1.15.1	Correspondence relating to promotional materials
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 and 601.45	Presubmission of launch promotional materials for accelerated approval products	1	1.15.1.3	Presubmission of launch promotional materials for accelerated approval products
314.550 and 601.45	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
Section 503B of the Federal Food, Drug, and Cosmetic Act	Promotional materials submitted pursuant to section 503B	1	1.15.1.5	Promotional materials submitted pursuant to section 503B
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

CFR Citation/Source		CTD /*STF Heading/**Attribute(s) Required		
NUMBER	TITLE	MODULE	NUMBER	TITLE
202.1	Correspondence accompanying materials previously missing or rejected	1	1.15.1.8	Correspondence accompanying materials previously missing or rejected
202.1	Withdrawal request	1	1.15.1.9	Withdrawal request
202.1	Submission of annotated references	1	1.15.1.10	Submission of annotated references
202.1	General correspondence	1	1.15.1.11	General correspondence
314.550 601.45	Subpart H: Promotional materials	1	1.15.2	**Materials <attribute = [promotional-material-doc-type]>
314.550 601.45	Subpart H: Promotional materials	1	1.15.2.1	**Material <attribute = [promotional-material-type]>
202.1	Clean version	1	1.15.2.1.1	Clean version
202.1	Annotated version	1	1.15.2.1.2	Annotated version
202.1	Annotated labeling version	1	1.15.2.1.3	Annotated labeling version
202.1	Annotated references	1	1.15.2.1.4	Annotated references
FDAMA	Risk evaluation and mitigation strategies (REMS)	1	1.16	Risk evaluation and mitigation strategies (REMS)
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 application: Clinical	5	As needed	Use appropriate sections
314.94(a)(2)	Table of Contents	N/A	N/A	N/A

Appendix 2 - Module 1 Summary of Changes (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]>
1.3.5.3	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
1.7.4	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
1.11.4	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
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

Module Section	Old Title	New Title
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	Professional labeling and patient labeling that accompanies promotional labeling pieces
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]
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

Module Section	Old Title	New Title
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