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

Module 1 Administrative information

1.1 Forms

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

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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
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1.4.3 List of authorized persons to incorporate by reference
1.4.4 Cross reference to other applications

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1.5.2 Inactivation request
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1.5.4 Reinstatement request
1.5.5 Withdrawal of an unapproved NDA
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1.6 Meetings

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1.6.2 Meeting background materials

2.6.6 Toxicology written summary
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2.7.2 Summary of Clinical Pharmacology studies
2.7.3 Summary of Clinical Efficacy [indication]
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Module 3 Quality

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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
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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
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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

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 heading

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 heading

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 heading

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 heading

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

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 heading

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 heading

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

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 heading

4.2.3.5.2 Embryofetal development

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for heading

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 heading

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 heading

4.2.3.6 Local tolerance

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for heading

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 heading

4.2.3.7.2 Immunotoxicity

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for heading

4.2.3.7.3 Mechanistic studies

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for heading

4.2.3.7.4 Dependence

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for heading

4.2.3.7.5 Metabolites

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for heading

4.2.3.7.6 Impurities

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for heading

4.2.3.7.7 Other

Study report [identification number] and related information

See Primary pharmacodynamics Study report and related information for heading

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 (E3 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

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

Mapping

IND

CFR Citation/Source		CTD /*STF Heading		
NUMBER	**TITLE**	**Module**	**NUMBER**	**TITLE**
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
PDUFA agreements	Rollin Review Request	1	1.7.5	Correspondence regarding CMA Pilot 2
FDAMA	Special protocol assessment request: Clinical study	1	1.8.1	Special protocol assessment request: Clinical study
PDUFA agreements	Special protocol assessment request: Carcinogenicity Study	1	1.8.1	Special protocol assessment request: Carcinogenicity study
PDUFA agreements	Special protocol assessment request: Stability study	1	1.8.1	Special protocol assessment request: Stability study
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 Proposed pediatric study request and amendments	1	1.9.4	Proposed Proposed pediatric study request and amendments
BPCA	Proposal for Written Agreement	1	1.9.5	Proposal for Written Agreement

PREA BPCA	Correspondence regarding pediatric exclusivity or PREA requirements	1	1.9.6	Correspondence regarding pediatric exclusivity or study plans
312.7(d)(1)	Charging for and commercialization of investigational drugs	1	1.12.3	Request to charge
312.10	Waivers	1	1.12.5	Request for a waiver
312.23(a)1	Cover sheet (Form FDA–1571).	1	1.1.1	Application form: FDA form 1571
312.23(a)(2)	Table of contents	N/A	N/A	N/A
312.23(a)(3)(i)	Introductory statement	2	2.2	Introduction to summary
312.23(a)(3)(ii-iii)	Introductory statement	2	2.5	Clinical overall summary
312.23(a)(3)(iv)	A brief description of the overall plan…	1	1.13.9	General investigational plan
312.23(a)(5)	Investigator brochure	1	1.14.4.1	Investigator brochure
312.23(a)(6)	Protocol	5	5.3	*Protocol [under specific study]
312.23(a)(7)(a), (b) and (c)	Chemistry, manufacturing and controls	2	2.3	Quality overall summary
312.23(a)(7)(a), (b) and (c)	Chemistry, manufacturing and controls	3	As needed	Quality [use appropriate sections]
312.23(a)7(d)	Labeling	1	1.14.4.2	Investigational Drug Labeling
312.23(a)(7)(iv)(e)	Environmental analysis requirements	1	1.12.14	Environmental analysis
312.23(a)(8)	Pharmacology and toxicology information	2	2.4	Nonclinical overview
312.23(a)(8)	Pharmacology and toxicology information	2	2.6	Nonclinical written and tabulated summaries [use appropriate sections]
312.23(a)(8)	Pharmacology and toxicology information	4	4.2	Study reports [use appropriate sections]
312.23(a)(9)	Previous human experience	2	2.5	Clinical overview
312.23(a)(9)	Previous human experience	2	2.7	Clinical summary [use appropriate sections]
312.23(a)(9)	Previous human experience	5	5.3	Clinical study reports and related information [use appropriate sections]

312.23(a)(10)(i)	Drug dependence and abuse	2	2.7.4	Summary of Clinical Safety
312.23(a)(10)(ii)	Radioactive drugs	2, 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)(11)	Relevant information	1, 2, 3, 4 or 5	As needed	Use appropriate sections
312.23(b)	Information previously submitted –by sponsor	1	1.4.4	Cross reference to other applications
312.23(c)	Material in a foreign language (English Translations)	1, 2, 3, 4, or 5	As needed	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]
312.31(a)(1),	Information amendment: Chemistry	3	As needed	Use appropriate sections
312.31(a)(1)	Information amendment: Chemistry -information not covered under Module 3	1	1.11.1	Quality information amendment (only for information not covered under Module 3
312.31(a)(1)	Information amendment: Toxicology	4	As needed	Use appropriate sections
312.31(a)(1)	Information amendment: Toxicology - information not covered under Module 4	1	1.11.2	Safety information amendment (only for information not covered under Module 4)
312.31(a)(1)	Information amendment: Clinical	5	As needed	Use appropriate sections
312.31(a)(1)	Information amendment: Clinical - information not covered under Module 5	1	1.11.3	Efficacy information amendment (only for information not covered under Module 5
312.31(a)(2)	Report regarding the discontinuation of a clinical investigation	1	1.12.9	Notification of discontinuation of clinical trial
312.31(b)(1)	Statement of the nature	1	1.2	Cover letter

	and purpose of the information amendment			
312.31(b)(3)	Request for comment on information amendment	1	1.12.4	Request for comments and advice
312.32	IND safety reports	5	5.3	*IND safety report [under specific study]
312.33(a)	Annual report individual study information	1	1.13.8	Individual study 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
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)(6)	Annual Report: A list of preclinical studies…	1	1.13.1	Summary of nonclinical studies
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	1.13.5	Summary of microbiological changes
312.33(c)	Annual Report: A description of the general investigational plan…	1	1.13.9	General investigational plan
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]

312.33(d)	Annual Report: Investigators brochure…	1	1.14.4.1	Investigator brochure
312.33(f)	Annual Report: A brief summary of significant foreign marketing developments…	1	1.13.10	Foreign marketing history
312.33(g)	Annual Report: Log of outstanding business…(optional)	1	1.13.14	Log of outstanding regulatory business
312.35(a)(1)	Treatment protocol	5	5.3	*Protocol [under specific study]
312.35(a)(2)(i)	Treatment protocol: Investigators brochure	1	1.14.4.1	Investigator brochure
312.35(a)(2)(ii)	Treatment protocol: Technical information…	3, 4, 5	As needed	Use appropriate sections
312.35(a)(2)(iii)	Treatment protocol: Compliance with informed consent	5	5.3	*List and description of investigators and sites [under specific study]
312.36	Emergency use of an investigational new drug	1, 2, 3, 4, 5	As Needed	Use appropriate sections
312.38	Withdrawal of an IND	1	1.5.1	Withdrawal Request
312.41	Comment and advice on an IND	1	1.12.4	Request for comments and advice
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
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 material
312.47 PDUFA Agreements	Correspondence regarding a meeting	1	1.6.3	Correspondence regarding a meeting
312.48 FDAMA	Request for dispute resolution	1	1.10.1	Request for a dispute resolution
312.48 FDAMA	Correspondence related to dispute resolution	1	1.10.2	Correspondence related to dispute resolution
312.52	Transfer of obligations to a	1	1.3.1.3	Transfer of obligation

	contract research organization.			
312.54	Exception from informed consent for research	1	1.12.6	Exception from informed consent for research
312.54	Public disclosure – exception from informed consent for research	1	1.12.7	Public disclosure statement for exception from informed consent for research
312.54	IRB disapproval of exception from informed consent for research	1	1.12.8	Correspondence regarding exception from informed consent for research
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]
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(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
312.120(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]

NDA

CFR Citation/Source		**CTD /*STF Heading**		
NUMBER	**TITLE**	**Module**	**NUMBER**	**TITLE**
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
PDUFA	Rolling Review	1	1.7.6	Correspondence

agreements	Request			regarding CMA Pilot 1
314.50(a)	Application form	1	1.1.2	Application form: FDA form 356h
PDUFA	User Fee Cover Sheet	1	1.1.3	User Fee Cover Sheet: FDA form 3397
GDEA	Debarment Certification	1	1.3.3	Debarment Certification
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	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
BPCA	Proposal for written agreement	1	1.9.5	Proposal for written agreement
PREA BPCA	Correspondence regarding pediatric exclusivity or PREA requirements	1	1.9.6	Correspondence regarding pediatric exclusivity or study pland
315.50(b)	Index	N/A	N/A	N/A
314.50(c)(2)(i)	The proposed text of the labeling with annotations	1	1.14.1.2	Annotated draft labeling text
314.50(c)(2)(ii) to (ix)	Summaries…	2	As needed	Use the appropriate sections
314.50(d)(1)(i) and (ii)	Chemistry, manufacturing and controls	3	As needed	Use the appropriate sections
314.50(d)(1)(iii)	Environmental impact	1	1.12.14	Environmental analysis
314.50(d)(1)(v)	Field copy certification	1	1.3.2	Field copy certification
314.50(d)(2)	Nonclinical pharmacological and toxicology section	4	As needed	Use appropriate sections
314.50(d)(3)	Human pharmacokinetics and bioavailability sections	5	5.3	Use appropriate sections
314.50(d)(4)	Microbiology	5	5.3.5.5	Other study reports and related information [Use appropriate sections in microbiology STF]
314.50(d)(5)(i)	Clinical data section	5	5.3	Use appropriate

to (iv)				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]
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)(5)(vii)	Potential for abuse	5	5.3	Use appropriate sections
314.50(d)(5)(viii)	An integrated summary of the benefits and risks	2	2.5	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)(x)	Transfer of obligations to CRO	1	1.3.1.4	Transfer of obligation
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(d)(7)	Pediatric use section	2 and 5	As needed	Use appropriate sections
314.50(e)(2)(i)	Analytical methods	3	As needed	Use appropriate sections
314.50(e)(2)(ii)	Copies of the labeling and all labeling for the drug product	1	1.14	Use appropriate sections
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(g)(1)	Written statement of authorization for references	1	1.4.1	Letter of authorization
314.50(g)(1)	Reference to information previously submitted by sponsor	1	1.4.4	Cross reference to other applications and information previously submitted in paper
314.50(g)(1)	Statement of right of reference	1	1.4.2	Statement of right of reference
314.50(h) 314.53(b)	Patent Information	1	1.3.5.1	Patent Information (Form FDA 3542a and FDA form 3542)
314.50(i) 314.52(b)	Patent certification	1	1.3.5.2	Patent certifications
314.50(j)	Claimed exclusivity	1	1.3.5.3	Exclusivity claim
314.50(k)	Financial certification and disclosure statement	1	1.3.4	Financial certification and disclosure
PREA	Pediatric studies: waiver of pediatric study requirements	1	1.9.1	Request for waiver of pediatric studies
PREA	Pediatric studies: deferrals of pediatric study requirements	1	1.9.2	Request for deferral of pediatric studies
314.60	Amendment to an unapproved application: Chemistry	3	As needed	Use appropriate sections
314.60	Amendment to an unapproved application: Chemistry (information not covered under Module 3)	1	1.11.1	Quality information amendment (only for information not covered under Module 3)
314.60	Amendment to an unapproved application: Toxicology	4	As needed	Use appropriate sections
314.60	Amendment to an unapproved application: Toxicology (information not covered under Module 4)	1	1.11.2	Safety information amendment (only for information not covered under Module 4)

314.60	Amendment to an unapproved application: Clinical	5	As needed	Use appropriate sections
314.60	Amendment to an unapproved application: Clinical (information not covered under Module 5)	1	1.11.3	Efficacy information amendment (only for information not covered under Module 5
314.65	Withdrawal of an unapproved application	1	1.5.5	Withdrawal of an unapproved application
314.70 and 314.71	Supplements and other changes to approved applications	1, 2, 3, 4, 5	As needed	Use the appropriate sections
314.72	Change of ownership of an application	1	1.3.1.4	Change in ownership of an application
314.80©(2)(ii)(a) 314.80©(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
314.81(b)(1)	Field alert reports	1	1.12.16	Field alert reports
314.81(b)(2)	Annual report transmittal: FDA form 2252	1	1.1.4	Annual Report Transmittal: FDA form 2252
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.1	Summary of nonclinical changes
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.2	Summary of clinical pharmacology changes
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.3	Summary of safety changes
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)(iii)	Annual Report: Labeling	1	1.14	Use appropriate sections
314.81(b)(2)(iv)	Annual Report: Chemistry,	3	As needed	Use appropriate sections

	manufacturing and controls			
314.81(b)(2)(v)	Annual Report: Nonclinical laboratory studies	4	As needed	Use appropriate sections
314.81(b)(2)(vi)	Annual Report: Clinical data	5	As needed	Use appropriate sections
314.81(b)(2)(vii)	Annual Report: Status report of clinical and nonclinical toxicology postmarketing study commitments	1	1.13.12	Status report of clinical and nonclinical toxicology postmarketing study commitments
314.81(b)(2)(viii)	Status report of other (chemistry, manufacturing, controls) postmarketing study commitments	1	1.13.13	Status of other postmarketing study commitments
314.81(b)(2)(ix)	Annual Report: Log of outstanding regulatory business	1	1.13.14	Log of outstanding regulatory business
314.81(b)(3)(i)	Advertising and promotional labeling	1	1.15	Promotional material
314.81(b)(3)(i)	Transmittal of Advertisements and Promotional Labeling	1	1.1.5	Advertisements and promotional labeling transmittal: FDA form 2253
314.90	Waivers	1	1.12.5	Request for a waiver
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
314.150(c)	Request for withdrawal of approval	1	1.5.7	Request for withdrawal of application approval
314.150(b)	Withdrawal or suspension of approval by the FDA	1	1.5.7	Other correspondence regarding status of application or product
314.420(a)	Drug master files	1, 2, 3, 4, 5	As Needed	Use appropriate sections
314.420(b)	Incorporating DMF information by	1	1.4.1	Letter of Authorization

	reference			
314.420(d)	List of authorized persons to incorporate by reference	1	1.4.3	List of authorized persons to incorporate by reference
314.550	Subpart H: Promotional materials	1	1.15	Promotional material
314.640	Subpart I: Promotional materials	1	1.15	Promotional material

ANDA

CFR Citation/Source		**CTD /*STF Heading**		
NUMBER	**TITLE**	**Module**	**NUMBER**	**TITLE**
314.94(a)(1)	Application form	1	1.2	Application form: FDA form 356h
GDEA	Debarment Certification	1	1.3.3	Debarment Certification
314.94(a)(2)	Table of Contents	N/A	N/A	N/A
314.94(a)(3)	Basis for abbreviated new drug application submission	1	1.11.11	Basis for submission statement
314.94(a)(4)	Conditions for use	1	1.11.11	Basis for submission statement
314.94(a)(5)	Active ingredient	1	1.11.12	Comparison of generic drug and reference listed drug
314.94(a)(6)	Route of administration, dosage form and strength	1	1.11.12	Comparison of generic drug and reference listed drug
314.94(a)(7)	Bioequilvance	5	5.3	Use appropriate sections
314.94(8)(i)	Listed drug labeling	1	1.14.3.2	Approved labeling text for listed drug
314.94(8)(ii)	Copies of proposed labeling	1	1.14	Use appropriate sections
314.94(8)(iii)	Statement of proposed labeling	1	1.14.3.1	Annotated comparison with listed drug
314.94(8)(iv)	Comparison of approved and proposed labeling	1	1.14.3.1	Annotated comparison with listed drug
314.94(9)	Chemistry, manufacturing and control	3	As needed	Use appropriate sections
314.94(11)	Reference to information previously submitted by sponsor	1	1.4.4	Cross reference to other applications
314.94(12)	Patent certification	1	1.3.5.2	Patent certification
314.95	Notice of certification	1	1.3.5.3	Certification of non-

	of non-validity or non-infringement of patent			validity or non-infringement of patent
314.94(13)	Financial certification and disclosure	1	1.3.4	Financial certification and disclosure
314.96	Amendment to an unapproved application: Chemistry	3	As needed	Use appropriate sections
314.96	Amendment to an unapproved application: Chemistry (information not fitting under module 3)	1	1.11.1	Quality information amendment
314.96	Amendment to an unapproved application: Clinical	5	As needed	Use appropriate sections
314.96	Amendment to an unapproved application: Clinical (information not fitting under module 5)	1	1.11.3	Efficacy information amendment
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
314.150(c)	Request for withdrawal of approval	1	1.5.7	Request for withdrawal of an application
314.150(b) 314.151	Withdrawal or suspension of approval by the FDA	1	1.5.7	Other correspondence regarding status of application or product
314.420(a)	Drug master files	1, 2, 3, 4, 5	As needed	Use appropriate sections
314.420(b)	Incorporating DMF information by reference	1	1.4.1	Letter of Authorization
314.420(d)	List of authorized persons to incorporate by reference	1	1.4.3	List of authorized persons to incorporate by reference