- 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 Product labeling for 2253 submissions

1.15 Promotional material [promotional-material-audience-type (R)]

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

Module 2 Summaries

- 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 (R)]
  - 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 [substance (O), manufacturer (O)]
    - 3.2.S.1 General information
    - 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 [descriptor (O)]
  - 3.2.P Drug product [product (O), dosage form (O), manufacturer (O)]
    - 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 [excipient (O)]

- 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 [container (O)]

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 [descriptor (O)]

3.2.A Appendices
- 3.2.A.1 Facilities and Equipment [facility (O)]
- 3.2.A.2 Adventitious agents safety evaluation [component (O)]
- 3.2.A.3 Novel excipients [excipient (O)]

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 id_study title (R)]

[document type (R)]

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

Data tabulation

Data tabulation dataset legacy

Data tabulation dataset send
Data tabulation data definition
Data listing data set
Data listing dataset
Data listing data definition
Analysis datasets
Analysis dataset adam
Analysis dataset legacy
Analysis program
Analysis data definition
Safety report
Assay validation
Biomarkers
Data monitoring review committees
Device information
Diagnostic tests
Gene therapy
Pharmacodynamics
Pharmacogenomics
Pharmacokinetics
Stem cells
Antibody
Other data not specified
PK PD relationship
Specialty report
Foreign clinical studies not under ind

4.2.1.2 Secondary pharmacodynamics
[study id_study title (R)]
[document type (R)]
See Primary pharmacodynamics above for available document types

4.2.1.3 Safety pharmacology
[study id_study title (R)]
[document type (R)]
See Primary pharmacodynamics above for available document types

4.2.1.4 Pharmacodynamic drug interactions
[study id_study title (R)]
[document type (R)]
See Primary pharmacodynamics above for available document types

4.2.2 Pharmacokinetics

4.2.2.1 Analytical methods and validation reports
[study id_study title (R)]
[document type (R)]
See Primary pharmacodynamics above for available document types

4.2.2.2 Absorption

Appendix 1 – Mapping Section

IND

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
312.23(a)(1)	Cover sheet (Form FDA–1571)	1	1.1
FDAAA	Certification of compliance: Form FDA 3674	1	1.1
BsUFA	Form FDA 3792: Biosimilar User Fee Cover Sheet	1	1.1
312.31(b)(1)	Statement of the nature and purpose of the information amendment	1	1.2
	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 in contact/agent NOTE: Includes DMF original contact/agent or change in DMF contact/agent	1	1.3.1.2
	Change in ownership	1	1.3.1.3
312.52	Transfer of obligations to a contract research organization	1	1.3.1.4
312.22(d)	General principles of the IND submission		1.4.1
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
312.23(b) 312.23(a)(3)(ii)	Information previously submitted	1	1.4.4
312.38	Withdrawal of an IND	1	1.5.1
312.45(a)	Request for Inactive status	1	1.5.2
312.45(d)	Request to resume clinical investigation under an inactive IND	1	1.5.3
	Reinstatement request	1	1.5.4

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
312.47 PDUFA Agreements	Meeting request	1	1.6.1
312.47 PDUFA Agreements	Meeting background material	1	1.6.2
312.47 PDUFA Agreements	Correspondence regarding a meeting	1	1.6.3
FDAMA	Fast track designation request	1	1.7.1
FDAMA	Fast track designation withdrawal request	1	1.7.2
FDAMA	Rolling review request	1	1.7.3
FDAMA	Correspondence regarding fast track/rolling review	1	1.7.4
FDAMA	Special protocol assessment request: clinical study	1	1.8.1
PDUFA Agreements	Special protocol assessment request: carcinogenicity study	1	1.8.2
PDUFA Agreements	Special protocol assessment request: stability study	1	1.8.3
	Animal efficacy study for approval under the animal rule	1	1.8.4.
PREA 312.47(b)(1)(iv)	Request for waiver of pediatric studies	1	1.9.1
PREA 312.82 312.47(b)(1)(iv)	Request for deferral of pediatric studies	1	1.9.2
BPCA	Proposed pediatric study request and amendments	1	1.9.4
PREA BPCA	Correspondence regarding pediatric exclusivity or PREA requirements	1	1.9.6
312.48	Scientific and medical disputes	1	1.10.1
312.48	Scientific and medical disputes	1	1.10.2
312.31	Information amendment: Chemistry - information not covered under Module 3	1	1.11.1
312.31	Information amendment: Toxicology - information not covered under Module 4	1	1.11.2
312.31	Information amendment: Clinical - information not covered under Module 5	1	1.11.3
312.31	Multiple Information amendment	1	1.11.4

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
312.82(a)	Pre-IND correspondence	1	1.12.1
312.8(b)	Charging for investigational drugs under an IND	1	1.12.2
312.8(c)	Charging for investigational drugs under an IND	1	1.12.3
312.31(b)(3)	Request for comment on information amendment	1	1.12.4
312.41	Comment and advice on an IND	1	1.12.4
312.10	Waivers (including PSUR waiver)	1	1.12.5
312.54	Exception from informed consent for research	1	1.12.6
312.54	Public disclosure – exception from informed consent for research	1	1.12.7
312.54	IRB disapproval of exception from informed consent for research	1	1.12.8
312.31(a)(2)	Report regarding the discontinuation of a clinical investigation	1	1.12.9
312.23(a)(7)(iv)(e)	Environmental analysis requirements	1	1.12.14
316 Subpart C	Orphan Drug	1	1.12.17
356(g)	Regenerative advanced therapy	1	1.12.18
312.33(b)(6)	Annual Report: A list of preclinical studies…	1	1.13.1
312.33(b)(5)	Annual Report: A brief description of the drug's actions…	1	1.13.2
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
312.33(b)(2)	Annual Report: A summary of all IND safety reports…	1	1.13.3
312.33(b)(3)	Annual Report: A list of subjects who died…	1	1.13.3
312.33(b)(4)	Annual Report: A list of subjects who dropped out…	1	1.13.3

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
312.33(b)(7)	Annual Report: A summary of any significant manufacturing changes…	1	1.13.5
312.33(b)(7)	Annual Report: A summary of any significant microbiological changes…	1	1.13.6
312.33(a)	Annual report individual study information	1	1.13.8
312.33(c)	Annual Report: A description of the general investigational plan…	1	1.13.9
312.33(f)	Annual Report: A brief summary of significant foreign marketing developments…	1	1.13.10
312.33(g)	Annual Report: Log of outstanding business…(optional)	1	1.13.14
	Development safety update report (DSUR)	1	1.13.15
312.6	Draft labeling text	1	1.14.1.3
	Label comprehension studies	1	1.14.1.4
312.23(a)(5)	Investigator brochure	1	1.14.4.1
312.33(d)	Annual Report: Investigators brochure…	1	1.14.4.1
312.23(a)(7)(iv)(d)	Labeling	1	1.14.4.2
	Foreign labeling	1	1.14.5
	Proprietary names	1	1.18
Project BioShield Act of 2004	Emergency Use Authorization	1	1.19
312.23(a)(3)(iv)	A brief description of the overall plan…	1	1.20
312.23(a)(3)(i)	Introductory statement	2	2.2
312.23(a)(7)(a), (b) and (c)	Chemistry, manufacturing, and controls	2	2.3
312.23(a)(8)	Pharmacology and toxicology information	2	2.4
312.23(a)(9)	Previous human experience	2	2.5
312.23(a)(3)(ii-iii)	Introductory statement	2	2.5
312.23(a)(8)	Pharmacology and toxicology information	2	2.6
312.23(a)(9)	Previous human experience	2	2.7
312.23(a)(10)(i)	Drug dependence and abuse	2	2.7.4

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
312.23(a)(8)	Pharmacology and toxicology information	4	4.2
312.23(a)(9)	Previous human experience	5	5.3
312.30(a)	New protocol	5	5.3
312.30(b)	Changes in protocol	5	5.3
312.30(c)	New investigator	5	5.3
312.23(a)(6)	Protocol	5	5.3
312.32	IND safety reports	5	5.3
312.33(e)	Annual Report: A description of any significant Phase 1 protocol modifications made during the previous years and….	5	5.3
312.320	Treatment protocol	5	5.3
312.120(b)(1)	Foreign clinical studies not conducted under the IND: Investigator's qualification	5	5.3
312.120(b)(2)	Foreign clinical studies not conducted under the IND: Research facility	5	5.3
312.120(b)(3)	Foreign clinical studies not conducted under the IND: Detailed summary	5	5.3
312.120(a)(1)	Foreign clinical studies not conducted under the IND: Conformance with ethical principles	5	5.3
312.23(a)(11)	Relevant information	1, 2, 3, 4, or 5	As needed
312.23(c)	Material in a foreign language (English translations)	1, 2, 3, 4, or 5	As needed
312.23(a)(10)(iv)	Other information	2, 3, 4, or 5	As needed
312.23(a)(10)(ii)	Radioactive drugs	2, 4, or 5	As needed
312.23(a)(7)(a), (b) and (c)	Chemistry, manufacturing and controls	3	As needed
312.31(a)(1),	Information amendment: Chemistry	3	As needed
312.120(b)(4)	Foreign clinical studies not conducted under the IND: A description of the drug substance and drug product	3	As needed

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
312.31	Information amendment: Toxicology	4	As needed
312.31	Information amendment: Clinical	5	As needed
312.23(a)(2)	Table of contents	N/A	N/A

NDA and BLA

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
314.50(a) 601.2	Application Form FDA 356h	1	1.1
PDUFA	User fee cover sheet: Form FDA 3397	1	1.1
BsUFA	Form FDA 3792: Biosimilar User Fee Cover Sheet	1	1.1
FDAAA	Certification of compliance: Form FDA 3674	1	1.1
314.81(b)(2)	Annual report transmittal: Form FDA 2252	1	1.1
314.81(b)(3)(i) 601.12(f)(4)	Transmittal of advertisements and promotional labeling: Form FDA 2253	1	1.1
601.12 (f)	Transmittal of labels and circulars: Form FDA 2567	1	1.1
	Cover letters	1	1.2
	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 in contact/agent NOTE: Includes DMF original contact/agent or change in DMF contact/agent	1	1.3.1.2
314.50(d)(5)(x)	Transfer of obligations to CRO	1	1.3.1.4
314.72 601.4	Change in ownership of an application	1	1.3.1.5
314.50(d)(1)(v)	Field copy certification	1	1.3.2
GDEA	Debarment certification	1	1.3.3
314.50(k) 601.2(a)	Financial certification and disclosure statement (Form FDA 3454 and Form FDA 3455)	1	1.3.4
314.50(h) 314.53(e)	Patent Information (Form FDA 3542a and Form FDA 3542)	1	1.3.5.1
314.50(i) 314.52(e)	Patent certification	1	1.3.5.2
314.50(j)	Claimed exclusivity	1	1.3.5.3
FDAAA	Tropical disease priority review voucher	1	1.3.6

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
314.420(d)	Incorporating DMF information by reference (authorization from DMF holder)	1	1.4.1
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
314.420(d)	List of authorized persons to incorporate by reference	1	1.4.3
314.50(g)(1)	Reference to information previously submitted	1	1.4.4
314.65	Withdrawal of an unapproved application	1	1.5.5
314.50	Withdrawal of listed drug	1	1.5.6
314.150(c)	Withdrawal of approval	1	1.5.7
314.150 601.5	Withdrawal of approval by the FDA	1	1.5.7
314.102	Communications: Meetings	1	1.6.1
314.102	Communications: Meetings	1	1.6.2
314.102	Communications: Meetings	1	1.6.3
FDAMA	Fast track designation request	1	1.7.1
FDAMA	Fast track designation withdrawal request	1	1.7.2
FDAMA	Rolling review request	1	1.7.3
FDAMA	Correspondence regarding fast track/rolling review	1	1.7.4
PREA 314.55(c) 601.27(c)	Request for waiver of pediatric studies	1	1.9.1
PREA 314.55(b) 601.27(b)	Request for deferral of pediatric studies	1	1.9.2
BPCA	Request for pediatric exclusivity determination/Form FDA 3437	1	1.9.3
BPCA	Proposed pediatric study request and amendments	1	1.9.4

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
PREA BPCA	Correspondence regarding pediatric exclusivity or PREA requirements	1	1.9.6
314.103(c)	Scientific and medical disputes	1	1.10.1
314.103(c)	Scientific and medical disputes	1	1.10.2
314.60	Amendment to an unapproved application: Chemistry (information not covered under Module 3)	1	1.11.1
314.60	Amendment to an unapproved application: Toxicology (information not covered under Module 4)	1	1.11.2
314.60	Amendment to an unapproved application: Clinical (information not covered under Module 5)	1	1.11.3
314.60	Multiple information amendment:	1	1.11.4
	Request for comment and advice	1	1.12.4
314.90 600.90	Waivers (including PSUR waiver)	1	1.12.5
GDEA	Generic drugenforcement act statement	1	1.12.10
314.50(d)(1)(iii) 601.2	Environmental impact	1	1.12.14
320.22 (a)	Request for waiver of in vivo bioavailability studies	1	1.12.15
314.81(b)(1)	Field alert reports	1	1.12.16
316 Subpart C	Orphan drug	1	1.12.17
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.1
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.2
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.3
314.81(b)(2)(i) 601.12(f)(3)	Annual Report: Summary	1	1.13.4
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.5
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.6
314.81(b)(2)(i) 601.12(d)	Annual Report: Summary	1	1.13.7
314.81(b)(2)(ii)	Annual Report: Distribution data	1	1.13.11

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
314.81(b)(2)(vii) 601.70	Annual Report: Status report of clinical and nonclinical toxicology postmarketing study commitments	1	1.13.12
314.81(b)(2)(viii)	Status report of other (chemistry, manufacturing, controls) postmarketing study commitments	1	1.13.13
314.81(b)(2)(ix)	Annual Report: Log of outstanding regulatory business	1	1.13.14
314.50(e)(2)(ii) 601.14	Copies of the labeling and all labeling for the drug product	1	1.14
314.81(b)(2)(iii) 601.14(f)(3)	Annual Report: Labeling	1	1.14
314.50 601.14	Draft carton and container labels	1	1.14.1.1
314.50(c)(2)(i)	The proposed text of the labeling with annotations	1	1.14.1.2
314.50(e)(2)(ii) 601.2 601.14	Draft labeling text	1	1.14.1.3
	Label comprehension studies	1	1.14.1.4
	Labeling history	1	1.14.1.5
314.50(e)(2)(ii) 601.2	Final carton or container labels	1	1.14.2.1
314.50(e)(2)(ii) 601.2; 601.14	Final package insert (package inserts, patient information, medication guides)	1	1.14.2.2
314.50(e)(2)(ii) 601.2; 601.14	Final labeling text	1	1.14.2.3
	Foreign labeling	1	1.14.5
314.81(b)(3)(i) 601.12(f)(4)	Product labeling for 2253 submissions (if applicable)	1	1.14.6
314.81(b)(3)(i) 601.12(f)(4) 314.550 601.45 202.1(j)(4) 314.640 601.94 202.1	Regulations related to promotional materials [use appropriate sections]	1	1.15
202.1(j)(4)	Request for advisory comments on launch materials	1	1.15.1.1

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
202.1(j)(4)	Request for advisory comments on non-launch materials	1	1.15.1.2
314.550 601.45	Presubmission of launch promotional materials for accelerated approval of products for serious or life-threatening illnesses	1	1.15.1.3
314.640 601.94	Presubmission of launch promotional materials for products approved when human efficacy studies are not ethical or feasible	1	1.15.1.3
314.550 601.45	Presubmission of non-launch promotional materials for accelerated approval of products for serious or life-threatening illnesses	1	1.15.1.4
314.640 601.94	Presubmission of non-launch promotional materials for products approved when human efficacy studies are not ethical or feasible	1	1.15.1.4
202.1 Section 503C of the Food, Drug, and Cosmetic Act	Pre-dissemination review of television ads	1	1.15.1.5
202.1	Response to untitled letter or warning letter	1	1.15.1.6
202.1	Response to information request	1	1.15.1.7
202.1 314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94	Correspondence accompanying materials previously missing or rejected	1	1.15.1.8
202.1 314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94	Withdrawal request	1	1.15.1.9

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
202.1 202.1(j)(4) 314.550 601.45 314.640 601.94	Submission of annotated references	1	1.15.1.10
202.1	General correspondence	1	1.15.1.11
314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Regulations related to promotional materials [use appropriate sections]	1	1.15.2
314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Regulations related to promotional materials [use appropriate sections]	1	1.15.2.1
202.1 314.81(b)(3)(i) 601.12(f)(4) 202.1(j)(4) 314.550 601.45 314.640 601.94	Clean version	1	1.15.2.1.1
202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Annotated version	1	1.15.2.1.2
202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Annotated labeling version	1	1.15.2.1.3

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
202.1(j)(4) 314.550 601.45 314.640 601.94 202.1	Annotated references	1	1.15.2.1.4
FDAAA 505-1 [355-1]	Risk evaluation and mitigation strategies (REMS)	1	1.16
FDAAA	Correspondence regarding postmarketing commitments	1	1.17.1
FDAAA	Correspondence regarding postmarketing requirements	1	1.17.2
	Proprietary names	1	1.18
314.50(d)(5)(viii)	An integrated summary of the benefits and risks	2	2.5
314.50(c)(2)(ii) to (ix)	Summaries…	2	As needed
314.50(d)(7)	Pediatric use section	2 and 5	As needed
314.50(d)(1)(i) and (ii)	Chemistry, manufacturing and controls	3	As needed
314.50(e)(2)(i)	Analytical methods	3	As needed
314.60	Amendment to an unapproved application: Chemistry	3	As needed
600.81	Distribution reports	3	3.2.R
314.81(b)(2)(iv)	Annual Report: Chemistry, manufacturing, and controls	3	As needed
314.50(d)(2)	Nonclinical pharmacological and toxicology section	4	As needed
314.81(b)(2)(v)	Annual Report: Nonclinical laboratory studies	4	As needed
314.60	Amendment to an unapproved application: Toxicology	4	As needed
314.50(d)(5)(ix)	Statement of compliance with informed consent	5	5.3
314.50(d)(5)(xi)	Audited studies	5	5.3
314.50(d)(6)(i) and (ii)	Description of statistical analysis	5	5.3
314.50(f)(1)	Case report tabulations	5	5.3
314.50(f)(2)	Case report forms	5	5.3
314.50(d)(5)(i) to (iv)	Clinical data section	5	5.3

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
314.50(d)(3)	Human pharmacokinetics and bioavailability sections	5	5.3
314.50(d)(5)(vii)	Potential for abuse	5	5.3
314.50(d)(5)(v)	An integrated summary of efficacy	5	5.3.5.3
314.50(d)(5)(vi)(a)	An integrated summary of safety	5	5.3.5.3
314.50(d)(5)(vi)(b)	Safety Update	5	5.3.5
314.50(d)(4)	Microbiology	5	5.3.5.4
314.80(c)(2)(ii)(a) 314.80(c)(2)(ii)(c) 600.80(c)(20(ii)(A) 600.80(c)(2)(ii)(C)	Periodic adverse drug experience – narrative summary and history of actions	5	5.3.6
314.70 and 314.71 601.12	Supplements and other changes to approved applications	1, 2, 3, 4, 5	As needed
314.420(a)	Drug master files	1, 2, 3, 4, 5	As needed
314.60	Amendment to an unapproved application: Clinical	5	As needed
314.81(b)(2)(vi)	Annual Report: Clinical data	5	As needed
315.50(b)	Index	N/A	N/A

ANDA

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
314.94(a)(1)	Application Form FDA 356h	1	1.1
GDUFA	Form FDA 3794: Generic Drug User Fee Cover Sheet	1	1.1
FDAAA	Certification of compliance: Form FDA 3674	1	1.1
	Transmittal of labels and circulars: Form FDA 2567	1	1.1
314.81(b)(2)	Annual report transmittal: Form FDA 2252	1	1.1
314.81(b)(3)(i)	Transmittal of advertisements and promotional labeling: Form FDA 2253	1	1.1
	Cover letters	1	1.2
	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 in contact/agent NOTE: Includes DMF original contact/agent or change in DMF contact/agent	1	1.3.1.2
314.72	Change in ownership of an application	1	1.3.1.5
314.50(d)(1)(v)	Field copy certification	1	1.3.2
Generic Drug Enforcement Act (GDEA)	Debarment certification	1	1.3.3
314.94(13)	Financial certification and disclosure (Form FDA 3454 and Form FDA 3455)	1	1.3.4
314.50(h) 314.53(e)	Patent information (Form FDA 3542a and Form FDA 3542)	1	1.3.5.1
314.94(12)	Patent certification	1	1.3.5.2
314.95	Notice of certification of nonvalidity or noninfringement of patent	1	1.3.5.3
314.420(d)	Incorporating DMF information by reference (authorization from DMF holder)	1	1.4.1

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
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
314.420(d)	List of authorized persons to incorporate by reference	1	1.4.3
314.94(11)	Reference to information previously submitted	1	1.4.4
314.65	Withdrawal of an unapproved application	1	1.5.5
314.150	Withdrawal of listed drug	1	1.5.6
314.150(c)	Request for withdrawal of approval	1	1.5.7
314.102	Communications: meetings	1	1.6.1
314.102	Communications: meetings	1	1.6.2
314.102	Communications: meetings	1	1.6.3
314.103(c)	Scientific and medical disputes	1	1.10.1
314.103(c)	Scientific and medical disputes	1	1.10.2
314.96	Amendment to an unapproved application: Chemistry (information not fitting under Module 3)	1	1.11.1
314.98	Amendment to an unapproved application: Toxicology (information not covered under Module 4)	1	1.11.2
314.96	Amendment to an unapproved application: Clinical (information not fitting under Module 5)	1	1.11.3
314.96	Multiple information amendment:	1	1.11.4
	Request for comment and advice	1	1.12.4
GDEA	Generic drug enforcement act statement	1	1.12.10
314.94(a)(3)	Basis for abbreviated new drug application submission	1	1.12.11
314.94(a)(4)	Conditions for use	1	1.12.11
314.94(a)(5)	Active ingredient	1	1.12.12
314.94(a)(6)	Route of administration, dosage form, and strength	1	1.12.12

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
25.15(d)	Environmental impact analysis statement (if applicable)	1	1.12.14
320.22 (a)	Request for waiver of in vivo bioavailability studies	1	1.12.15
314.81(b)(i)(ii)	Field alert reports	1	1.12.16
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.1
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.2
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.3
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.4
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.5
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.6
314.81(b)(2)(i)	Annual Report: Summary	1	1.13.7
314.81(b)(2)(ii)	Annual Report: Distribution data	1	1.13.11
314.81(b)(2)(vii)	Annual Report: Status report of clinical and nonclinical toxicology postmarketing study commitments	1	1.13.12
314.81(b)(2)(viii)	Status report of other (chemistry, manufacturing, controls) postmarketing study commitments	1	1.13.13
314.81(b)(2)(ix)	Annual Report: Log of outstanding regulatory business	1	1.13.14
314.94(a)(8)(ii)	Copies of proposed labeling [Use appropriate sections]	1	1.14.1
314. 94(a)(8)(ii)	Draft carton and container labels	1	1.14.1.1
314.50(c)(2)(i)	The proposed text of the labeling with annotations	1	1.14.1.2
314.94(a)(8)(ii)	Draft labeling text	1	1.14.1.3
314.94(a)(8)(ii)	Final carton or container labels	1	1.14.2.1
314.94(a)(8)(ii)	Final package insert (package inserts, patient information, medication guides)	1	1.14.2.2
314.94(a)(8)(ii)	Final labeling text	1	1.14.2.3
314.94(a)(8)(iii)	Statement of proposed labeling	1	1.14.3.1
314.94(a)(8)(iv)	Comparison of approved and proposed labeling	1	1.14.3.1
314.94(a)(8)(i)	Listed drug labeling	1	1.14.3.2
314.94(a)(8)(i)	Labeling text for reference listed drug	1	1.14.3.3

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
314.81(b)(3)(i)	Product labeling for 2253 submissions (if applicable)	1	1.14.6
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Regulations related to promotional materials [use appropriate sections]	1	1.15
202.1 202.1(j)(4)	Request for advisory comments on launch materials	1	1.15.1.1
202.1 202.1(j)(4)	Request for advisory comments on non-launch materials	1	1.15.1.2
202.1 314.550	Presubmission of launch promotional materials for accelerated approval products	1	1.15.1.3
202.1 314.640	Presubmission of launch promotional materials for products approved when human efficacy studies are not ethical or feasible	1	1.15.1.3
202.1 314.550	Presubmission of non-launch promotional materials for accelerated approval products	1	1.15.1.4
314.640	Presubmission of non-launch promotional materials for products approved when human efficacy studies are not ethical or feasible	1	1.15.1.4
202.1 Section 503C of the Federal Food, Drug, and Cosmetic Act	Pre-dissemination review of television ads	1	1.15.1.5
202.1	Response to untitled letter or warning letter	1	1.15.1.6
202.1	Response to information request	1	1.15.1.7
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Correspondence accompanying materials previously missing or rejected	1	1.15.1.8

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Withdrawal request	1	1.15.1.9
202.1 202.1(j)(4) 314.550 314.640	Submission of annotated references	1	1.15.1.10
202.1	General correspondence	1	1.15.1.11
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Regulations related to submission of promotional materials [use appropriate sections]	1	1.15.2
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Regulations related to promotional materials [use appropriate sections]	1	1.15.2.1
202.1 314.81(b)(3)(i) 202.1(j)(4) 314.550 314.640	Clean version	1	1.15.2.1.1
202.1 202.1(j)(4) 314.550 314.640	Annotated version	1	1.15.2.1.2
202.1 202.1(j)(4) 314.550 314.640	Annotated labeling version	1	1.15.2.1.3
202.1 202.1(j)(4) 314.550 314.640	Annotated references	1	1.15.2.1.4
FDAAA 505-1 [355-1]	Risk evaluation and mitigation strategies (REMS)	1	1.16
FDAAA	Correspondence regarding postmarketing commitments	1	1.17.1
FDAAA	Correspondence regarding postmarketing requirements	1	1.17.2
314.420(a)	Drug master files	1, 2, 3, 4, 5	As needed

CFR Citation/Source		CTD Section	
NUMBER	**TITLE**	**MODULE**	**NUMBER**
314.96	Amendment to an unapproved application: Chemistry	3	As needed
314.94(9)	Chemistry, manufacturing, and control	3	As needed
314.94(a)(7)	Bioequivalence	5	5.3
314.96	Amendment to an unapproved application: Clinical	5	As needed
314.94(a)(2)	Table of Contents	N/A	N/A

Appendix 2 –Summary of Changes

Module Section	Old Title	New Title	Change Notes
Module 1/Regional Changes			
1.12		1.12.18 Regenerative medicine advanced therapy (RMAT) designation	Added new heading and mapping to CFR
1.18	1.18 Proprietary Names	1.18 Naming 1.18.1 Proprietary names 1.18.2 Biological Proper Name Suffix	Renamed section and added subheadings
Module 2-5			
2.3	2.3 Quality overall summary	2.3 Quality overall summary	Added sub-headings for this section
		2.3.I Introduction	Added new heading
		2.3.S Drug substance [substance (O), manufacturer (O)]	Added new heading and optional keyword
		2.3.P Drug product [product (O), dosage form (O)]	Added new heading and optional keyword
		2.3.A Appendices	Added new heading for new subsections
		2.3.A.1 Facilities and equipment [facility (O)]	Added new heading and optional keyword
		2.3.A.2 Adventitious agents safety evaluation [component (O)]	Added new heading and optional keyword
		2.3.A.3 Excipients	Added new heading
		2.3.R Regional information	Added new heading
3.2.S	3.2.S Drug substance [name, manufacturer]	3.2.S Drug substance [substance (O), manufacturer (O)]	Made keywords optional for 3.2.S
3.2.S.1	3.2.S.1.1 Nomenclature 3.2.S.1.2 Structure 3.2.S.1.3 General properties		Removed subheadings
3.2.S.7.3	3.2.S.7.3 Stability Data	3.2.S.7.3 Stability Data [descriptor (O)]	Added new optional keyword

Module Section	Old Title	New Title	Change Notes
3.2.P.4	3.2.P.4 Control of excipients[name]	3.2.P.4 Control of excipients [excipient (O)]	Removed name and added new optional keyword
3.2.P.7	3.2.P.7 Container closure system	3.2.P.7 Container closure system [container (O)]	Added new optional keyword
3.2.P.8.3	3.2.P.8.3 Stability Data	3.2.P.8.3 Stability Data [descriptor (O)]	Added new optional keyword
3.2.A	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.A.1 Facilities and Equipment [facility (O)] 3.2.A.2 Adventitious agents safety evaluation [component (O)] 3.2.A.3 Novel excipients [excipient (O)]	Changed keywords allowed for these sections
4	Study report [identification number] and related information	[study id_study Title]	For all applicable sections in Module 4, the study id and study title have been concatenated into one keyword
5	Study report [identification] and related information	[study id_study Title]	For all applicable sections in Module 5, the study id and study title have been concatenated into one keyword