# **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

#### 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 request

### 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 other applications

# 1.5 Application status

- 1.5.1 Withdrawal request
- 1.5.2 Inactivation request
- 1.5.3 Reactivation request
- 1.5.4 Reinstatement request
- 1.5.5 Withdrawal of an unapproved NDA
- 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

# 1.8 Special protocol assessment request

- 1.8.1 Clinical study
- 1.8.2 Carcinogenicity study
- 1.8.3 Stability study

# 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
- 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

### 1.12 Other correspondence

- 1.12.1 Pre IND correspondence
- 1.12.2 Request to charge
- 1.12.3 Notification of charging under treatment IND
- 1.12.4 Request for comments and advice
- 1.12.5 Request for a waiver
- 1.12.6 Exemption from informed consent for research
- 1.12.7 Public disclosure statement for exception from informed consent for research
- 1.12.8 Correspondence regarding exception from informed consent for research
- 1.12.9 Notification of discontinuation of clinical trial
- 1.12.10 Generic drug enforcement act statement
- 1.12.11 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

### 1.13 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 history
- 1.13.11 Distribution data
- 1.13.12 Status of postmarketing study commitments
- 1.13.13 Status of other postmarketing studies
- 1.13.14 Log of outstanding regulatory business

# 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
- 1.15 Promotional material
- 1.16 Risk management plans

### **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 Post-approval 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
- 3.3Literature 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 heading

# 4.2.1.4 Pharmacodynamic drug interactions

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

#### 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 heading

#### 4.2.2.2 Absorption

Study report [identification number] and related information

See Primary pharmacodynamics Study report and
related information for heading

# 4.2.2.3 Distribution

Study report [identification number] and related information

See Primary pharmacodynamics Study report and
related information for heading

#### 4.2.2.4 Metabolism

Study report [identification number] and related information

See Primary pharmacodynamics Study report and
related information for heading

#### **4.2.2.5 Excretion**

Study report [identification number] and related information

See Primary pharmacodynamics Study report and
related information for heading

### 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 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

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

# 5.3.2.1 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

# **Mapping**

IND

| CFR Citation/Source |                         |     | CTD /*STF Heading |                         |  |
|---------------------|-------------------------|-----|-------------------|-------------------------|--|
| NUMBER              | TITLE                   | Mod | NUMBER            | TITLE                   |  |
|                     |                         | ule |                   |                         |  |
| FDAMA               | Fast Track Designation  | 1   | 1.7.1             | Fast Track Designation  |  |
|                     | Request                 |     |                   | Request                 |  |
| FDAMA               | Fast Track Designation  | 1   | 1.7.2             | Fast Track Designation  |  |
|                     | Withdrawal Request      |     |                   | Withdrawal Request      |  |
| FDAMA               | Rolling Review Request  | 1   | 1.7.3             | Rolling Review          |  |
|                     |                         |     |                   | Request                 |  |
| PDUFA               | Rollin Review Request   | 1   | 1.7.5             | Correspondence          |  |
| agreements          |                         |     |                   | regarding CMA Pilot 2   |  |
| FDAMA               | Special protocol        | 1   | 1.8.1             | Special protocol        |  |
|                     | assessment request:     |     |                   | assessment request:     |  |
|                     | Clinical study          |     |                   | Clinical study          |  |
| PDUFA               | Special protocol        | 1   | 1.8.1             | Special protocol        |  |
| agreements          | assessment request:     |     |                   | assessment request:     |  |
|                     | Carcinogenicity Study   |     |                   | Carcinogenicity study   |  |
| PDUFA               | Special protocol        | 1   | 1.8.1             | Special protocol        |  |
| agreements          | assessment request:     |     |                   | assessment request:     |  |
|                     | Stability study         |     |                   | Stability study         |  |
| PREA                | Request for waiver of   | 1   | 1.9.1             | Request for waiver of   |  |
|                     | pediatric studies       |     |                   | pediatric studies       |  |
| PREA                | Request for deferral of | 1   | 1.9.2             | Request for deferral of |  |
|                     | pediatric studies       |     |                   | pediatric studies       |  |
| BPCA                | Proposed Proposed       | 1   | 1.9.4             | Proposed Proposed       |  |
|                     | pediatric study request |     |                   | pediatric study request |  |
|                     | and amendments          |     |                   | and amendments          |  |
| BPCA                | Proposal for Written    | 1   | 1.9.5             | Proposal for Written    |  |
|                     | Agreement               |     |                   | Agreement               |  |

| PREA<br>BPCA             | Correspondence regarding pediatric      | 1   | 1.9.6     | Correspondence regarding pediatric   |
|--------------------------|---|-----|-----------|--|
| DI CA                    | exclusivity or PREA requirements        |     |           | exclusivity or study   |
| 312.7(d)(1)              | Charging for and commercialization of   | 1   | 1.12.3    | Request to charge  |
|                          | investigational drugs                   |     |           |  |
| 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:<br>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-<br>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),         | Chemistry,                              | 2   | 2.3       | Quality overall  |
| (b) and (c)              | manufacturing and controls              |     |           | summary  |
| 312.23(a)(7)(a),         | Chemistry,                              | 3   | As needed | Quality [use   |
| (b) and (c)              | manufacturing and controls              |     |           | appropriate sections]  |
| 312.23(a)7(d)            | Labeling                                | 1   | 1.14.4.2  | Investigational Drug<br>Labeling   |
| 312.23(a)(7)(iv)(<br>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<br>and related information<br>[use appropriate<br>sections] |

| 312.23(a)(10)(i)  | Drug dependence and  | 2      | 2.7.4        | Summary of Clinical      |
|-------------------|--|--------|--------------|--------------------------|
| 312.23(u)(10)(1)  | abuse  |        | 2.7.1        | Safety                   |
| 312.23(a)(10)(ii) | Radioactive drugs  | 2, 4   | As needed    | Use appropriate          |
|                   |  | or 5   | 115 110 0000 | sections                 |
| 312.23(a)(10)(iv) | Other information  | 2, 3,  | As needed    | Use appropriate          |
|                   |  | 4 or 5 | 115 110 0000 | sections                 |
| 312.23(a)(11)     | Relevant information   | 1, 2,  | As needed    | Use appropriate          |
| 012.20(0)(11)     |  | 3, 4   | 115 110 0000 | sections                 |
|                   |  | or 5   |              |                          |
| 312.23(b)         | Information previously   | 1      | 1.4.4        | Cross reference to other |
|                   | submitted –by sponsor  |        |              | applications             |
| 312.23(c)         | Material in a foreign  | 1, 2,  | As needed    | Use appropriate          |
|                   | language (English  | 3, 4,  |              | sections                 |
|                   | Translations)  | or 5   |              |                          |
| 312.30(a)         | New protocol   | 5      | 5.3          | Protocol [under          |
| 012100(0)         | Trow protocol  |        |              | specific study]          |
| 312.30(b)         | Changes in protocol  | 5      | 5.3          | Protocol [under          |
|                   | Comment of the control of the cont |        |              | specific study]          |
| 312.30(c)         | New investigator   | 5      | 5.3          | List and description of  |
| 012.00(0)         | Tive with Configurer   |        |              | investigators and sites  |
|                   |  |        |              | [under specific study]   |
| 312.31(a)(1),     | Information amendment:   | 3      | As needed    | Use appropriate          |
| 012.01(0)(1),     | Chemistry  |        | 115 110000   | sections                 |
| 312.31(a)(1)      | Information amendment:   | 1      | 1.11.1       | Quality information      |
|                   | Chemistry -information   |        |              | amendment (only for      |
|                   | not covered under  |        |              | information not          |
|                   | Module 3   |        |              | covered under Module     |
|                   |  |        |              | 3                        |
| 312.31(a)(1)      | Information amendment:   | 4      | As needed    | Use appropriate          |
| . , , ,           | Toxicology   |        |              | sections                 |
| 312.31(a)(1)      | Information amendment:   | 1      | 1.11.2       | Safety information       |
|                   | Toxicology - information   |        |              | amendment (only for      |
|                   | not covered under  |        |              | information not          |
|                   | Module 4   |        |              | covered under Module     |
|                   |  |        |              | 4)                       |
| 312.31(a)(1)      | Information amendment:   | 5      | As needed    | Use appropriate          |
|                   | Clinical   |        |              | sections                 |
| 312.31(a)(1)      | Information amendment:   | 1      | 1.11.3       | Efficacy information     |
|                   | Clinical - information not   |        |              | amendment (only for      |
|                   | covered under Module 5   |        |              | information not          |
|                   |  |        |              | covered under Module     |
|                   |  |        |              | 5                        |
| 312.31(a)(2)      | Report regarding the   | 1      | 1.12.9       | Notification of          |
|                   | discontinuation of a   |        |              | discontinuation of       |
|                   | clinical investigation   |        |              | clinical trial           |
| 312.31(b)(1)      | Statement of the nature  | 1      | 1.2          | Cover letter             |

|              | 1 0.1                      |   |        |                         |
|--------------|----------------------------|---|--------|-------------------------|
|              | and purpose of the         |   |        |                         |
|              | information amendment      |   | 1.12.1 |                         |
| 312.31(b)(3) | Request for comment on     | 1 | 1.12.4 | Request for comments    |
|              | information amendment      |   |        | and advice              |
| 312.32       | IND safety reports         | 5 | 5.3    | *IND safety report      |
|              |                            |   |        | [under specific study]  |
| 312.33(a)    | Annual report individual   | 1 | 1.13.8 | Individual study        |
|              | study information          |   |        | information             |
| 312.33(b)(1) | Annual Report: A           | 1 | 1.13.3 | Summary of safety       |
|              | narrative or tabular       |   |        | information             |
|              | summary showing the        |   |        |                         |
|              | most frequent and most     |   |        |                         |
|              | serious adverse            |   |        |                         |
|              | experiences by the body    |   |        |                         |
|              | system                     |   |        |                         |
| 312.33(b)(2) | Annual Report: A           | 1 | 1.13.3 | Summary of safety       |
|              | summary of all IND         |   |        | information             |
|              | safety reports             |   |        |                         |
| 312.33(b)(3) | Annual Report: A list of   | 1 | 1.13.3 | Summary of safety       |
|              | subjects who died          |   |        | information             |
| 312.33(b)(4) | Annual Report: A list of   | 1 | 1.13.3 | Summary of safety       |
|              | subjects who dropped       |   |        | information             |
|              | out                        |   |        |                         |
| 312.33(b)(5) | Annual Report: A brief     | 1 | 1.13.2 | Summary of clinical     |
|              | description of the drug's  |   |        | pharmacology            |
|              | actions                    |   |        | information             |
| 312.33(b)(6) | Annual Report: A list of   | 1 | 1.13.1 | Summary of              |
|              | preclinical studies        |   |        | nonclinical studies     |
| 312.33(b)(7) | Annual Report: A           | 1 | 1.13.5 | Summary of              |
|              | summary of any             |   |        | manufacturing changes   |
|              | significant manufacturing  |   |        |                         |
|              | changes                    |   |        |                         |
| 312.33(b)(7) | Annual Report: A           | 1 | 1.13.5 | Summary of              |
|              | summary of any             |   |        | microbiological         |
|              | significant                |   |        | changes                 |
|              | microbiological            |   |        |                         |
|              | changes                    |   |        |                         |
| 312.33(c)    | Annual Report: A           | 1 | 1.13.9 | General investigational |
|              | description of the general |   |        | plan                    |
|              | investigational plan       |   |        | r ··                    |
| 312.33(e)    | Annual Report: A           | 5 | 5.3    | *Protocol [under the    |
| (-)          | description of any         | _ |        | specific study]         |
|              | significant Phase 1        |   |        |                         |
|              | protocol modifications     |   |        |                         |
|              | made during the previous   |   |        |                         |
|              | years and                  |   |        |                         |
| L            | yours and                  |   | 1      |                         |

| 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:<br>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,<br>3, 4,<br>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<br>PDUFA<br>Agreements | Meeting request  | 1                   | 1.6.1     | Meeting request   |
| 312.47<br>PDUFA<br>Agreements | Meeting background material  | 1                   | 1.6.2     | Meeting background material   |
| 312.47<br>PDUFA<br>Agreements | Correspondence regarding a meeting   | 1                   | 1.6.3     | Correspondence regarding a meeting                                      |
| 312.48<br>FDAMA               | Request for dispute resolution   | 1                   | 1.10.1    | Request for a dispute resolution  |
| 312.48<br>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<br>statement for exception<br>from informed consent<br>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<br>and consent forms<br>[under specific study]                  |

# NDA

| CFR Citation/Source |                        | CTD /*STF Heading |        |                        |
|---------------------|------------------------|-------------------|--------|------------------------|
| NUMBER              | TITLE                  | Module            | NUMBER | TITLE                  |
| FDAMA               | Fast Track Designation | 1                 | 1.7.1  | Fast Track Designation |
|                     | Request                |                   |        | Request                |
| FDAMA               | Fast Track Designation | 1                 | 1.7.2  | Fast Track Designation |
|                     | Withdrawal Request     |                   |        | Withdrawal Request     |
| FDAMA               | Rolling Review         | 1                 | 1.7.3  | Rolling Review         |
|                     | Request                |                   |        | Request                |
| FDAMA               | Correspondence         | 1                 | 1.7.4  | Correspondence         |
|                     | regarding Fast         |                   |        | regarding Fast         |
|                     | Track/Rolling Review   |                   |        | 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                           | 1   | 1.3.3     | Debarment  |
|                                 | Certification                       |     |           | Certification                                    |
| PREA                            | Request for waiver of               | 1   | 1.9.1     | Request for waiver of                            |
|                                 | pediatric studies                   |     |           | pediatric studies                                |
| PREA                            | Request for deferral of             | 1   | 1.9.2     | Request for deferral of                          |
|                                 | pediatric studies                   |     |           | pediatric studies                                |
| BPCA                            | Request for pediatric               | 1   | 1.9.3     | Request for pediatric                            |
|                                 | exclusivity                         |     |           | exclusivity                                      |
|                                 | determination                       |     |           | determination                                    |
| BPCA                            | Proposed pediatric                  | 1   | 1.9.4     | Proposed pediatric                               |
|                                 | study request and                   |     |           | study request and                                |
|                                 | amendments                          |     |           | amendments                                       |
| BPCA                            | Proposal for written                | 1   | 1.9.5     | Proposal for written                             |
|                                 | agreement                           |     |           | agreement  |
| PREA                            | Correspondence                      | 1   | 1.9.6     | Correspondence                                   |
| BPCA                            | regarding pediatric                 |     |           | regarding pediatric                              |
|                                 | exclusivity or PREA                 |     |           | exclusivity or study                             |
|                                 | requirements                        |     |           | pland  |
| 315.50(b)                       | Index                               | N/A | N/A       | N/A  |
| 314.50(c)(2)(i)                 | The proposed text of                | 1   | 1.14.1.2  | Annotated draft                                  |
|                                 | the labeling with                   |     |           | labeling text                                    |
|                                 | annotations                         |     |           |  |
| 314.50(c)(2)(ii)                | Summaries                           | 2   | As needed | Use the appropriate                              |
| to (ix)                         |                                     |     |           | sections   |
| 314.50(d)(1)(i)                 | Chemistry,                          | 3   | As needed | Use the appropriate                              |
| and (ii)                        | manufacturing and                   |     |           | sections   |
|                                 | controls                            |     |           |  |
| 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                         | 4   | As needed | Use appropriate                                  |
|                                 | pharmacological and                 |     |           | sections   |
|                                 | toxicology section                  |     |           |  |
| 314.50(d)(3)                    | Human                               | 5   | 5.3       | Use appropriate                                  |
|                                 | pharmacokinetics and                |     |           | sections   |
|                                 | bioavailability sections            |     |           |  |
|                                 | 1                                   |     | 1 5 2 5 5 |  |
| 314.50(d)(4)                    | Microbiology                        | 5   | 5.3.5.5   | Other study reports and                          |
| 314.50(d)(4)                    | Microbiology                        | 5   | 5.3.5.5   | related information                              |
| 314.50(d)(4)                    | Microbiology                        | 5   | 3.3.3.3   | related information [Use appropriate             |
| 314.50(d)(4)                    | Microbiology                        | 5   | 5.3.5.5   | related information [Use appropriate sections in |
| 314.50(d)(4)<br>314.50(d)(5)(i) | Microbiology  Clinical data section | 5   | 5.3.5.5   | related information [Use appropriate             |

| to (iv)                     |  |         |           | sections   |
|-----------------------------|--|---------|-----------|--|
| 314.50(d)(5)(v)             | An integrated summary of efficacy                            | 5       | 5.3.4     | Reports of analysis of<br>data from more than<br>one study [Use<br>appropriate sections in<br>integrated summary of<br>efficacy STF] |
| 314.50(d)(5)(vi)(<br>a)     | An integrated summary of safety                              | 5       | 5.3.4     | Reports of analysis of<br>data from more than<br>one study [Use<br>appropriate sections in<br>integrated summary of<br>safety STF]   |
| 314.50(d)(5)(vi)(<br>b)     | Safety Update  | 5       | 5.3.5     | Reports of analysis of<br>data from more than<br>one study [Use<br>appropriate sections in<br>integrated summary of<br>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<br>and consent forms<br>[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)<br>and (ii) | Description of statistical analysis                          | 5       | 5.3       | *Documentation of<br>statistical methods and<br>interim analysis plans<br>[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<br>tabulations [use the<br>appropriate sections<br>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)<br>314.53(b) | Patent Information  | 1 | 1.3.5.1   | Patent Information<br>(Form FDA 3542a and<br>FDA form 3542)                                 |
| 314.50(i)<br>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:<br>waiver of pediatric<br>study requirements                             | 1 | 1.9.1     | Request for waiver of pediatric studies   |
| PREA                   | Pediatric studies:<br>deferrals of pediatric<br>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<br>amendment (only for<br>information not<br>covered under Module<br>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<br>amendment (only for<br>information not<br>covered under Module<br>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<br>amendment (only for<br>information not<br>covered under Module<br>5 |
| 314.65                                 | Withdrawal of an unapproved application   | 1                | 1.5.5     | Withdrawal of an unapproved application   |
| 314.70 and<br>314.71                   | Supplements and other changes to approved applications                                    | 1, 2, 3,<br>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)<br>314.80©(2)(ii)(c) | Periodic adverse drug<br>experience – narrative<br>summary and history of<br>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<br>transmittal: FDA form<br>2252  | 1                | 1.1.4     | Annual Report<br>Transmittal: FDA form<br>2252  |
| 314.81(b)(2)(i)                        | Annual Report:<br>Summary   | 1                | 1.13.1    | Summary of nonclinical changes  |
| 314.81(b)(2)(i)                        | Annual Report:<br>Summary   | 1                | 1.13.2    | Summary of clinical pharmacology changes  |
| 314.81(b)(2)(i)                        | Annual Report:<br>Summary   | 1                | 1.13.3    | Summary of safety changes   |
| 314.81(b)(2)(i)                        | Annual Report:<br>Summary   | 1                | 1.13.4    | Summary of labeling changes   |
| 314.81(b)(2)(i)                        | Annual Report:<br>Summary   | 1                | 1.13.5    | Summary of manufacturing changes  |
| 314.81(b)(2)(i)                        | Annual Report:<br>Summary   | 1                | 1.13.6    | Summary of microbiological changes  |
| 314.81(b)(2)(i)                        | Annual Report:<br>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:<br>Labeling  | 1                | 1.14      | Use appropriate sections  |
| 314.81(b)(2)(iv)                       | Annual Report:<br>Chemistry,  | 3                | As needed | Use appropriate sections  |

|                      | manufacturing and                                |          |           |                          |
|----------------------|--|----------|-----------|--------------------------|
|                      | manufacturing and                                |          |           |                          |
| 21 1 21 (1 ) (2) ( ) | controls   |          |           |                          |
| 314.81(b)(2)(v)      | Annual Report:                                   | 4        | As needed | Use appropriate          |
|                      | Nonclinical laboratory                           |          |           | sections                 |
|                      | studies  |          |           |                          |
| 314.81(b)(2)(vi)     | Annual Report:                                   | 5        | As needed | Use appropriate          |
|                      | Clinical data                                    |          |           | sections                 |
| 314.81(b)(2)(vii)    | Annual Report: Status                            | 1        | 1.13.12   | Status report of         |
|                      | report of clinical and                           |          |           | clinical and nonclinical |
|                      | nonclinical toxicology                           |          |           | toxicology               |
|                      | postmarketing study                              |          |           | postmarketing study      |
|                      | commitments                                      |          |           | commitments              |
| 314.81(b)(2)(viii    |  | 1        | 1.13.13   | Status of other          |
| 314.01(0)(2)(VIII    | Status report of other                           | 1        | 1.13.13   |                          |
| )                    | (chemistry,                                      |          |           | postmarketing study      |
|                      | manufacturing,                                   |          |           | commitments              |
|                      | controls) postmarketing                          |          |           |                          |
|                      | study commitments                                |          |           |                          |
| 314.81(b)(2)(ix)     | Annual Report: Log of                            | 1        | 1.13.14   | Log of outstanding       |
|                      | outstanding regulatory                           |          |           | regulatory business      |
|                      | business   |          |           |                          |
| 314.81(b)(3)(i)      | Advertising and                                  | 1        | 1.15      | Promotional material     |
|                      | promotional labeling                             |          |           |                          |
| 314.81(b)(3)(i)      | Transmittal of                                   | 1        | 1.1.5     | Advertisements and       |
|                      | Advertisements and                               | _        | 11110     | promotional labeling     |
|                      | Promotional Labeling                             |          |           | transmittal: FDA form    |
|                      | 1 Tomotional Labeling                            |          |           | 2253                     |
| 314.90               | Waivers  | 1        | 1.12.5    | Request for a waiver     |
| 314.102              | Communications:                                  | 1        | 1.6.1     | Meeting request          |
| 314.102              | Meetings   | 1        | 1.0.1     | Meeting request          |
| 214 102              |  | 1        | 1.60      | Magting background       |
| 314.102              | Communications:                                  | 1        | 1.6.2     | Meeting background       |
| 21110                | Meetings   |          | 1.50      | materials                |
| 314.102              | Communications:                                  | 1        | 1.6.3     | Correspondence           |
|                      | Meetings   |          |           | regarding meetings       |
| 314.103(c)           | Scientific and medical                           | 1        | 1.10.1    | Request for dispute      |
|                      | disputes   |          |           | resolution               |
| 314.103(c)           | Scientific and medical                           | 1        | 1.10.2    | Correspondence related   |
| , ,                  | disputes   |          |           | to dispute resolution    |
| 314.150(c)           | Request for withdrawal                           | 1        | 1.5.7     | Request for withdrawal   |
| (-)                  | of approval                                      | _        |           | of application approval  |
| 314.150(b)           | Withdrawal or                                    | 1        | 1.5.7     | Other correspondence     |
|                      | suspension of approval                           | 1        | 1.5.7     | regarding status of      |
|                      | by the FDA                                       |          |           |                          |
| 214.420(a)           | <del>1                                    </del> | 1 2 2    | As Nooded | application or product   |
| 314.420(a)           | Drug master files                                | 1, 2, 3, | As Needed | Use appropriate          |
| 21.4.420.73          | T  | 4, 5     | 1.4.1     | sections                 |
| 314.420(b)           | Incorporating DMF                                | 1        | 1.4.1     | Letter of Authorization  |
|                      | information by                                   |          |           |                          |

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

|                     | materials               |                   |           |                          |  |
|---------------------|-------------------------|-------------------|-----------|--------------------------|--|
| 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               | 1                 | 1.3.3     | Debarment                |  |
|                     | Certification           |                   |           | Certification            |  |
| 314.94(a)(2)        | Table of Contents       | N/A               | N/A       | N/A                      |  |
| 314.94(a)(3)        | Basis for abbreviated   | 1                 | 1.11.11   | Basis for submission     |  |
|                     | new drug application    |                   |           | statement                |  |
|                     | submission              |                   |           |                          |  |
| 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                | 1                 | 1.11.12   | Comparison of generic    |  |
|                     | administration, dosage  |                   |           | drug and reference       |  |
|                     | form and strength       |                   |           | 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      | 1                 | 1.14      | Use appropriate          |  |
|                     | labeling                |                   |           | sections                 |  |
| 314.94(8)(iii)      | Statement of proposed   | 1                 | 1.14.3.1  | Annotated comparison     |  |
|                     | labeling                |                   |           | with listed drug         |  |
| 314.94(8)(iv)       | Comparison of           | 1                 | 1.14.3.1  | Annotated comparison     |  |
|                     | approved and proposed   |                   |           | with listed drug         |  |
|                     | labeling                |                   |           |                          |  |
| 314.94(9)           | Chemistry,              | 3                 | As needed | Use appropriate          |  |
|                     | manufacturing and       |                   |           | sections                 |  |
| 21121111            | control                 |                   |           |                          |  |
| 314.94(11)          | Reference to            | 1                 | 1.4.4     | Cross reference to other |  |
|                     | information previously  |                   |           | applications             |  |
| 21.1.0.1/12         | submitted by sponsor    | 4                 | 1055      | D                        |  |
| 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-  |          |           | validity or non-        |
|------------|--------------------------|----------|-----------|-------------------------|
|            | infringement of patent   |          |           | infringement of patent  |
| 314.94(13) | Financial certification  | 1        | 1.3.4     | Financial certification |
| , ,        | and disclosure           |          |           | and disclosure          |
| 314.96     | Amendment to an          | 3        | As needed | Use appropriate         |
|            | unapproved               |          |           | sections                |
|            | application: Chemistry   |          |           |                         |
| 314.96     | Amendment to an          | 1        | 1.11.1    | Quality information     |
|            | unapproved               |          |           | amendment               |
|            | application: Chemistry   |          |           |                         |
|            | (information not fitting |          |           |                         |
|            | under module 3)          |          |           |                         |
| 314.96     | Amendment to an          | 5        | As needed | Use appropriate         |
|            | unapproved               |          |           | sections                |
|            | application: Clinical    |          |           |                         |
| 314.96     | Amendment to an          | 1        | 1.11.3    | Efficacy information    |
|            | unapproved               |          |           | amendment               |
|            | application: Clinical    |          |           |                         |
|            | (information not fitting |          |           |                         |
|            | under module 5)          |          |           |                         |
| 314.102    | Communications:          | 1        | 1.6.1     | Meeting request         |
|            | meetings                 |          |           |                         |
| 314.102    | Communications:          | 1        | 1.6.2     | Meeting background      |
|            | meetings                 |          |           | materials               |
| 314.102    | Communications:          | 1        | 1.6.3     | Correspondence          |
|            | meetings                 |          |           | regarding meetings      |
| 314.103(c) | Scientific and medical   | 1        | 1.10.1    | Request for dispute     |
|            | disputes                 |          |           | resolution              |
| 314.103(c) | Scientific and medical   | 1        | 1.10.2    | Correspondence related  |
|            | disputes                 |          |           | to dispute resolution   |
| 314.150(c) | Request for withdrawal   | 1        | 1.5.7     | Request for withdrawal  |
|            | of approval              |          |           | of an application       |
| 314.150(b) | Withdrawal or            | 1        | 1.5.7     | Other correspondence    |
| 314.151    | suspension of approval   |          |           | regarding status of     |
|            | by the FDA               |          |           | application or product  |
| 314.420(a) | Drug master files        | 1, 2, 3, | As needed | Use appropriate         |
| , ,        |                          |          |           | sections                |
| 314.420(b) | Incorporating DMF        | 4, 5     | 1.4.1     | Letter of Authorization |
| , ,        | information by           |          |           |                         |
|            | reference                |          |           |                         |
| 314.420(d) | List of authorized       | 1        | 1.4.3     | List of authorized      |
|            | persons to incorporate   |          |           | persons to incorporate  |
|            | by reference             |          |           | by reference            |