Guidance for Industry

Submitting Marketing Applications According to the ICH-CTD Format — General Considerations

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication of the *Federal Register* notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20857. All comments should be identified with the docket number listed in the notice of availability that published in the *Federal Register.*

For questions on the draft document contact Randy Levin (CDER) 301-594-5400 or Robert Yetter (CBER) 301-827-0373.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

August 2001

Procedural

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Food and Drug Administration
1401 Rockville Pike, Rockville, MD 20852-1448
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Guidance for Industry[1] Submitting Marketing Applications According to the ICH-CTD Format — General Considerations

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. INTRODUCTION

This is one in a series of guidance documents that provide recommendations for applicants preparing a Common Technical Document for the Registration of Pharmaceuticals for Human Use (CTD) for submission to the U.S. Food and Drug Administration (FDA). This guidance document is intended to describe how to organize new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biological license applications (BLAs) based on the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines on the CTD. This guidance document is intended to be used together with the CTD guidances, described below, and when finalized, it will supercede *Guidelines on Formatting, Assembling, and Submitting of New Drug and Antibiotic Applications* (February 1987*)* and the guidance for industry, *Organization of an ANDA* (February 1998).

Through the ICH process, considerable harmonization has been achieved among the three regions (Japan, Europe, and the United States) in the organization of a submission for the registration of pharmaceuticals for human use. The CTD format and organization are presented in a series of four documents, known as the CTD guidances. The four guidances, which will be issued in summer 2001, are titled:

- *M4: Organization of the CTD*
- *M4E: The CTD — Efficacy*
- *M4Q: The CTD — Quality*
- *M4S: The CTD — Safety*

These CTD guidance documents apply to applications for drug and biological pharmaceuticals (including biotechnology-derived products) and all related presubmissions, supplements, and amendments. The CTD guidance documents are not intended to indicate what data or studies are

[1] This guidance was developed by the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration.

required; they merely indicate an appropriate *format* for the data that have been acquired. The CTD guidance documents are intended to be used together with other ICH and Agency guidance documents that provide detailed information about the contents of an application. Applicants should not modify the overall organization of the CTD.

This guidance document presents general considerations for the overall organization and format of the marketing application based on the table of contents described in the CTD guidances. The marketing application is organized into five modules. This guidance describes the format (e.g., table of contents) of the region-specific administrative and prescribing information required by the United States in Module 1. The CTD guidances describe the format and organization of the Summaries, Quality, Nonclinical, and Clinical modules (Modules 2 to 5).

This guidance addresses the organization of an application provided entirely in paper, but we also accept NDAs and BLAs in electronic format. In the United States, regulations are in place that allow you to provide marketing applications in electronic format without a paper copy. In addition, for electronic submissions, applicants can provide documents as structured data, rather than traditional documents. We have considered these issues generally in this guidance document. The ICH M2 expert working group is developing ICH guidelines for providing the CTD in electronic format.

II. BACKGROUND

To market a drug or biological product in the United States, you must provide adequate information to the FDA demonstrating that the product is safe and effective for the conditions prescribed, recommended, or suggested in the proposed labeling for the product. The regulations under 21 CFR 314.50, 314.94, and 601.2 describe the information required for the NDA and ANDA for drug products and the BLA for biological products, respectively.

Substantial documentation and data are required in NDA, ANDA, and BLA submissions, resulting in large, complex applications. It is not a simple matter to compile the information or to review it. Applicants have used many different approaches to organizing the information, but differences in the organization of each application make reviewing more difficult and may lead to omission of critical data or analyses. Such omissions can result in a decision to refuse to file (RTF) an application. Previous guidance has been provided on how to organize various parts of a submission, but because of differing regional requirements, applicants who wanted to make submissions to more than one region had to prepare multiple, region-specific submissions. Through the ICH process, the CTD guidances have been developed. These guidances describe a common format for the organization of applications that can be used to support registration of pharmaceuticals for human use in Japan, the European Union, and the United States.

Although the content of the application is not significantly changed by the CTD guidances, the organization of the information described in the CTD guidances represents a change from the way applications are currently arranged in the three regions. We believe having a standard document with common elements will facilitate the development of applications and the

regulatory review process and will improve communication among applicants and the three regions.

We are now able to accept and review applications organized as described in the CTD guidances. You can submit a BLA for a specified biotechnological product, and an NDA or an ANDA for all drug products, in the CTD format. You can submit BLAs in CTD format for other categories of biological products as guidance documents become available for those product categories. If you wish to submit BLAs in the CTD format for those products ***prior*** to the availability of guidance, you should contact the CBER office with review responsibility prior to developing the submission. The Agency highly recommends that, by 2003, sponsors regularly submit BLAs for specified biotechnological products, NDAs, and ANDAs to the Agency in the CTD format.

An application organized as described in this guidance will fulfill the regulatory format requirements for 21 CFR 314.50, 314.94, and 601.2.

III. CTD FORMAT FOR EACH SUBMISSION

According to the CTD format, each submission of a marketing application is a collection of documents, grouped into 5 modules as listed in table 1. This guidance provides information on the contents of Module 1: *Administrative and Prescribing Information*, which is region specific. This guidance also discusses the general organization of Modules 2 to 5, which make up the CTD part of the application. The ***content*** of the documents contained in the CTD modules is outside the scope of this guidance. Appendix A lists some ICH and FDA documents that discuss content and other organizational issues related to each module.

No changes in regulations are needed to implement the CTD guidance for submission of an NDA, ANDA, or BLA. Appendix B lists the location of regulatory requirements for NDAs, ANDAs, and BLAs in relationship to the modules.

Table 1: Documents in each Module

Module	Information
1	Administrative and prescribing information (region specific)
2	Summaries and overview
3	Information on product quality
4	Nonclinical study reports
5	Clinical study reports

A. Module 1 - Administrative and Prescribing Information

Module 1 should contain all administrative documents (e.g., application forms, claims of categorical exclusion and certifications), and labeling, including the documents described

below, as needed.[2] Documents should be organized in the order listed below. Generally, all of the documents in Module 1 can be provided in a single volume. Environmental assessments should be submitted separately.

1. FDA form 356h

The first document in Module 1 should be FDA form 356h.

2. Comprehensive table of contents

The next document in Module 1 should be the comprehensive table of contents for the entire submission. Each NDA and ANDA submission is required to have a comprehensive table of contents or index for the entire submission as described in 21 CFR 314.50 and 314.94. The comprehensive table of contents significantly enhances the usefulness of the document. It should include a complete list of all documents provided in the submission by module.

In the table of contents, you should identify the location of each document by referring to the volume numbers that contain the relevant documents and any tab identifiers. In general, the name for the tab identifier should be the name of the document (e.g., patent certification, financial disclosure) or section heading according to the CTD format (e.g., 3.2.P.4.2). If the full name of the document is too long for the tab identifiers, you should substitute an alternative name that adequately identifies the document. You should not use page numbers in the table of contents to refer to documents, but use tab identifiers as described above.

3. Administrative documents

a. Administrative documents

You should provide the appropriate administrative documents with the submission. Examples of administrative documents are listed below. See 21 CFR 314.50, 314.94, and 601.2 for details on the administrative documents needed for specific submissions. FDA form 356h lists most of the administrative documents to be included in Module 1. The order of such documents should be consistent with that in FDA Form 356h.

- Patent information on any patent that claims the drug, if applicable
- Patent certifications (not for BLA)
- Debarment certification
- Field copy certification (not for BLA)
- User fee cover sheet
- Financial disclosure information

[2] Applicants often choose to submit a cover letter with their submissions. If you plan to include a cover letter, it should be placed at the beginning of Module 1.

- Letters of authorization for reference to other applications or drug master files
- Waiver requests
- Environmental assessment or request for categorical exclusion
- Statements of claimed exclusivity and associated certifications

Since these documents are small, you should place them in the same volume, separated by tab identifiers. If you submit an environmental assessment, you should provide it as a separate volume.

b. Prescribing information

You should include all copies of the labels and all labeling for the product in Module 1. The type of labeling provided depends on the submission. Examples of prescribing information include container and package labels as well as package inserts, draft labeling, patient leaflets, information sheets, and required Medication Guides. You should separate each sample of labeling by tab identifiers.

c. Annotated labeling text

For the NDA, you should provide a copy of the proposed labeling text with annotations directing reviewers to the information in the summaries and other modules that support each statement in the labeling, as described in 21 CFR 314.50(c)(2)(i). The annotated labeling text should include the content of the labeling described under 21 CFR 201.57 and all text, tables, and figures used in the package insert.

d. Labeling comparison

For the ANDA, you should provide the comparison of labeling that is described in 21 CFR 314.94(a)(8).

B. Module 2 – Common Technical Document Summaries

Module 2 should include the summary documents. You should provide the documents for this module in the order described below.

1. Overall CTD table of contents

For the first document in this module, you should provide a comprehensive table of contents listing all of the documents provided in the submission for modules 2 through 5.

2. Introduction to the summary documents

You should provide the introduction to the summary described in the guidance document *M4: Organization of the CTD* as a one page document.

3. Overviews and summaries

Module 2 should contain the following additional documents as described in the appropriate guidance documents (M4Q: The CTD -Quality, M4S: The CTD - Safety, M4E: The CTD – Efficacy):

- Quality overall summary (2.3, Module 2, section 3)
- Non clinical overview (2.4)
- Clinical overview (2.5)
- Nonclinical summary (2.6)
- Clinical summary (2.7)

The nonclinical summary and the clinical summary should be provided in separate volumes for ease of use by reviewers.

C. Module 3 - Quality

Module 3 should include information on the drug or biological substance and product that should be provided in the order described below. See Appendix A for additional recommendations on the content and organization of module 3.

1. Module 3 table of contents

The first document in this module should be a table of contents listing all of the documents provided for module 3. See the guidance document *M4Q: The CTD Quality* for the headings and order to be used in the table of contents, including numbering of section headings.

2. Body of data

Each individual subsection related to the drug or biological substance and product should be provided as an individual document either bound separately or divided by tab identifiers, depending on the size of the subsection. The documents should be presented in the order in which they are listed in the table of contents.

3. Literature References

Each literature reference should be provided as an individual document, separated from the others by tab identifiers.

D. Module 4 - Nonclinical Study Reports

Module 4 should contain the nonclinical study reports and related information. You should provide the documents for this module in the order described below.

1. Module 4 table of contents

The first document in this module should be a table of contents listing all of the documents provided for module 4. See the guidance to industry *M4S: The CTD – Safety* for the headings and order to be used in the table of contents, including numbering of section headings.

2. Study reports and related information

You should provide each study report and each related document as an individual document, separated from the other documents by binders or tab identifiers. These documents should be presented in the order in which they are listed in the table of contents.

3. Literature References

Each literature reference should be provided as an individual document, separated from the others by tab dividers.

E. Module 5 - Clinical Study Reports

Module 5 should contain clinical study reports and related information. You should provide the documents for this module in the order described below.

1. Module 5 table of contents

The first document in this module should be a table of contents listing all of the documents provided in Module 5. See the guidance to industry *M4E: The CTD - Efficacy* for the headings and order to be used in the table of contents, including numbering of section headings.

2. Study reports and related information

You should provide each study report and each related document, such as tabular listings of all clinical studies, as an individual document separated from the other documents by binders or tab dividers. We recommend that tab identifiers be provided for each appendix in a study report. These documents should be presented in the order in which they are listed in the table of contents.

The submission of a separate ISE and/or ISS is not required when the information provided can be incorporated into the CTD summaries and overview. When the ISS or ISE is submitted, it should be included in Module 5.3.5.3, Meta-Analyses. The applicant should raise any questions concerning the ISS and ISE with FDA staff prior to submission of the application.

You should include any case report forms (CRF) as separate documents. The case report forms should be organized by study.

The individual patient listings or case report tabulations (CRT) should include all of the clinical data collected in each study, organized by domain of data (e.g., adverse event, laboratory, physical examination). Each domain of data should be provided as a separate document. As with the CRFs, the CRTs should be organized by study.

3. Literature References

Each literature reference should be provided as an individual document separated from the others by tab identifiers.

IV. GENERAL ISSUES FOR SUBMISSIONS

Regulations in 21 CFR 314.50, 314.94, and 601.2 provide general requirements for submitting NDAs, ANDAs, and BLAs, respectively. This section addresses briefly some general issues related to providing marketing applications in paper format.

A. Amendments and Supplements

Although the CTD describes the agreed to common format for the preparation of the original application, you can use it for supplements to an original application or amendments to either the original application or subsequent supplements. General correspondence should be included in Module 1.

You can use the CTD format for submissions whether or not the previous submission was in the CTD format. You should not mix the CTD and older formats in the same module. We will consider, on a case-by-case basis, accepting submissions where some modules are provided in the CTD format and the rest of the submission is not in the CTD format. You should discuss this possibility at the pre NDA/BLA meeting or earlier.

B. Organizing Documents

You should bind all documents in separate volumes, or documents can be combined in volumes as long as they are separated by appropriately named tab identifiers. For example, the user fee cover sheet for a submission should be separated from the other documents by a tab identifier named *user fee cover sheet*. In general, documents from different CTD modules should not be included in the same volume. You may want to combine documents from different modules in the same volume for amendments consisting of a small number of short documents.

C. Number of copies

The regulations require archival, review, and field copies of NDAs and ANDAs. For BLAs, archival and review copies are generally submitted. The archival copy includes the entire submission. The review and field copies require only a portion of the application (see below).

1. Archival copy

The archival copy is a complete copy of the application. It serves as the official archive of the application and may be used during the review of the application.

2. Review copy

Review copies are in addition to the archival copy and include the information needed by each review discipline for its evaluation. These copies facilitate the concurrent review of the application by the different review disciplines. Review copies that may be necessary according to 21 CFR 314.50 for an individual submission include:

- Quality (Module 3),
- Nonclinical (Module 4),
- Clinical (Module 5) - safety and efficacy documents for clinical reviewer
- Clinical (Module 5) - safety and efficacy documents for the statistical reviewer,
- Clinical (Module 5) - clinical pharmacology and pharmacokinetics documents (or bioequivalence documents for ANDAs) , and
- Clinical (Module 5) – clinical microbiology documents.

You should include a copy of Modules 1 and 2 in each review copy. Each review copy should be labeled and bound separately.

It is recommended that you contact the office with the responsibility for the review of your product to determine how many copies of each module or sections of modules should be submitted.

3. Field copy

The field copy should be a separately bound copy of the Quality section (Module 3) for the NDA and ANDA. You should send this copy directly to the appropriate field office. A field copy is not required for the BLA.

D. Paper size

You should use standard U.S. letter size paper (8.5 x 11 inches) for all submissions. Occasionally, you may want to use individual pages larger than standard paper size to present a floor plan, synthesis diagram, batch formula, or manufacturing instructions. These pages should be folded and mounted so they may be opened for review without disassembling the jacket and refolded without damage when the volume is shelved.

E. Paper margins

We have found that a margin of at least 0.75 inches from the bound edge of the printed page prevents information from being obscured when the paper is placed in a binder. Other margins can be as small as 0.25 inches from the edge of the page. You can submit documents printed on both sides of a page, provided legibility is not impaired and margin space is sufficient on both the left and right side, so that information is not obscured when the page is placed in a binder.

F. Fonts

Font size for text and tables should be of a style and size that is large enough to be easily legible, even after photocopying or when provided electronically. We recommend that narrative text be submitted in Times New Roman 12 point font. Generally, font sizes 9 to 10 points are considered acceptable in tables, but you should avoid fonts smaller than 12 points whenever possible. When choosing a font size for tables, it is important to balance the desirability of providing sufficient information on a single page to facilitate data comparisons with that of maintaining a font size that remains readable. If the font size is too large, data comparisons may be complicated because data may be presented in multiple tables. Ten point font is recommended for footnotes.

G. Binding volumes

All pages should be submitted with three holes punched on the left side of the page and bound with fasteners, rather than placed in ring binders.

We recommend using polyvinyl type binders (0.23 to 0.25 gauge) for the archival copies and extra heavy paper binders for the review and field copies. A limited number of binders can be obtained by calling the number below. The quantity that can be ordered at any one time is determined by the U.S. Government Printing Office (GPO). Additional information regarding binders may be obtained by accessing the FDA Internet site: http://www.fda.gov/cder/ddms/binders.htm.

U. S. Government Printing Office
Washington, D.C. 20404-0001
(202) 512-1800
Program #B511-S

Additional binders can be purchased from commercial sources.

The front cover of the binder should be 9 by 11.5 inches, and the back cover should be 9 by 12 inches. You should use colored binders to distinguish the different copies of the applications. The archival copy should be blue. For ANDAs, the review copy should be red. For ANDAs and NDAs, the field copy should be green. The color for the NDA or BLA review copy binders depends on the type of information in the copy. See Table 2 for details.

Table 2: Binder Colors for NDA and BLA Review Copies

Review copy for:	Binder color
Quality	Red
Nonclinical	Yellow
Clinical- pharmacokinetics and bioavailability	Orange
Clinical – microbiology	White
Clinical - safety and efficacy - clinical	Tan
Clinical - safety and efficacy – statistical	Green

H. Volume size

Volumes should not be more than 2 inches thick. Volumes thicker than 2 inches are difficult for both the document room personnel and reviewers to handle.

I. Volume numbering

You should number the volumes by module, resulting in a separate set of numbers for each module.

J. Volume identification

You should print the following information prominently in the central portion of the front cover of each volume:

- Name of applicant
- Name of product
- Application number, if available
- Module number and name

On the front, lower right hand corner of each binder, you should print the volume number in the following format: *x of y volumes* where x is the number for the specific volume and y is the total number of volumes submitted for the respective module. For example, volume 6 for the Safety module with a total of 50 volumes for the module would have *6 of 50 volumes* in the lower right hand corner. The volumes in the module copy should be numbered sequentially.

On the front, upper right hand corner, you should print "Module __Volume ___". You should fill in this blank for the initial submission of the application using the format *Module m Volume s.x,* where *m* is the module number, *s* is the sequence number of the submission and *x* is the number of the specific volume in each module. For example, if the first submission for an application is a chemistry presubmission, volume 15 of the presubmission would be named *Module* 3, *Volume 1.15*.

All copies of the submission, including the review copies, should use the same volume numbers. However, the volume numbers may not be consecutive in the review copy since the review copy may only include a portion of the information in the archival copy.

K. Pagination

Page numbering should be at the document level and not at the volume or module level. (The entire submission should never be numbered consecutively by page.) In general, all documents should have page numbers. Since the page numbering is at the document level, there should only be one set of page numbers for each document.

If you include a document within a document, such as a protocol within a study report, the document to be included (in this case, the protocol) should be attached as an appendix. You should demarcate each appendix with an appropriately named tab identifier. For example, if the protocol is the first appendix, the tab should be named *Appendix A* or *Protocol* or some equivalent.

L. Cross referencing documents

You should reference documents by volume, CTD module, tab identifier, and page number.

M. Packing carton

To help us in storing submission volumes, we ask that you ship the volumes in boxes measuring 14 x 12 x 9.5 inches. On the outside of the carton, you should include the following information:

- Applicant's name
- Drug/biologic name
- Volume numbers included in the box
- Boxes should be numbered 1 of n, 2 of n, 3 of n, and so on.
- Type of copy included in the box (e.g., archival, clinical, safety, and efficacy review copy)

N. Sending the Submission

1. CBER

Send all submissions to the Document Control Center (DCC). The address for the DCC can be found at the CBER web site at www.fda.gov/cber.

2. CDER

For the NDA, you should send the initial paper submission to the central document room. You should send all other submissions to the appropriate division document room for

NDAs or, for ANDAs, to the Office of Generic Drugs. The addresses for the document rooms can be found at the CDER web site at www.fda.gov/cder. All submissions with electronic components should be sent to the central document room.

V. ELECTRONIC SUBMISSION

We currently accept marketing applications in electronic format. See the guidance *Providing Regulatory Submissions in Electronic Format - General Considerations* (January 1999), *Providing Regulatory Submissions in Electronic Format – NDA* (January 1999) and *Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format - Biologics Marketing Applications* (November 1999) for details on how to organize the documents for an electronic submission. We will continue to accept marketing applications in this electronic format.

ICH is working on guidance on providing an electronic CTD. When we are ready to accept electronic CTDs, we will publish guidance on that process. You can adapt the CTD to our current process for electronic submissions as described below. The table of contents files in the electronic submission should be the same as in a paper submission. However, you should divide the table of contents as described in the *Providing Regulatory Submissions in Electronic Format* guidance documents so each folder in the electronic submission has a table of contents as follows:

- Summary table of contents - you can place all of the Module 2 summary documents in the summary folder and use the Module 2 table of contents
- Quality table of contents - you can use the Module 3 table of contents in place of the CMC table of contents
- Clinical table of contents - you can divide the table of contents for the clinical study reports into one for the human pharmacology and bioavailability/ bioequivalence studies; one for microbiology study reports, if applicable; one for the efficacy and safety studies; one for CRTs; and one for CRFs. The tabular listing for all clinical studies should be included in table of contents for all study reports.

VI. QUESTIONS ABOUT PREPARING AND SENDING SUBMISSIONS

A. CBER

Send an email to cber@fda.gov with questions concerning paper submissions and esubprep@cber.fda.gov with questions concerning electronic submissions.

B. CDER

Send an email to cder@fda.gov with questions concerning paper submissions and esub@cder.fda.gov with questions concerning electronic submissions.

APPENDIX A: CONTENT OF THE CTD

The following table lists guidances and other publications relevant to the ***content*** of the modules in the CTD. All FDA and ICH guidance documents are available on the Internet at www.fda.gov/cder/regulatory/guidance/index.htm and www.fda.gov/cber/guidelines.htm, for CDER and CBER, respectively.

Module	**Refer to Other Guidance Documents**
General Information on the content of a submission	See FDA Form 356h
Module 1	*Submitting Applications According to the ICH/CTD Format —- General Considerations* (this guidance)
Module 2	See ICH guidances.
Module 3	Drug or biological substance and product guidance documents - *Drug Product: Format and Content for Submission of New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) Drug Substance* - Refer also to the regulations at 21 CFR 314.94 Specific subjects like botanicals, metered dose inhalers and nasal products, packaging, and stability are addressed in topic specific guidances
Module 4	See M2 ICH guidances. See also ICH guidances S1A and S4.
Module 5	Integrated summary of safety section - Guideline for the Format and Content of the Clinical and Statistical Sections of an Application, July 1988, page 32 to 46 Integrated summary of efficacy section - *Guideline for the Format and Content of the Clinical and Statistical Sections of an Application*, July 1988, page 28 to 32

APPENDIX B: REGULATORY REQUIREMENTS AND THE CTD

No changes in regulations are needed to implement the CTD guidelines. The following table lists the location of regulatory requirements in relationship to the CTD modules.

CTD	NDA: 314.50	ANDA: 314.94 (unless otherwise indicated)	BLA: 601.2 (unless otherwise indicated)
Module 1	(a) application form	(a)(1)application form	(a) application form
	(c)(2)(i) annotated text of proposed labeling	(a)(2) table of contents	
	(d)(1)(v) statement of field copy	(a)(3) basis for ANDA submission	
	(e) samples and labeling	(a)(4) conditions of use	(a) Labels, enclosures and medication guides
	(h) patent information	(a)(5) active ingredients	306(k)(1) and (2) debarment certification/list of convictions (FDC Act)
	(i) patent certification	Section 306(k)(1) and (2) debarment certification/list of convictions (FDC Act)	
	(j) claimed exclusivity	(a)(6) route of administration, dosage form and strength	
	(k) financial certification or disclosure	(a)(8) labeling requirements	
		(a)(12) patent certification	
		(a)(13) financial certifications or disclosure statement	(a) financial certification or disclosure statement
		(d)(5) certification of field copy	(a) claim of categorical exclusion or environmental assessment

Module 2	(b) comprehensive table of contents	N/A	
	(c) summaries		(a) summaries
	(d)(5)(vii) abuse potential		
Module 3	(d)(1) cmc	(a)(9) cmc	(a) full description of manufacturing methods
		(a)(10) samples	(a) samples
Module 4	(d)(2) nonclinical pharmtox	N/A	(a) data from non-clinical studies
Module 5	(d)(3) human pharmacokinetics	(a)(7)bioequivalence/bioavailability information	
	(d)(4) microbiology	320.22(d)(2)(i) waiver of in vivo BA/BE	
	(d)(5) clinical data		(a) data from clinical studies
	(d)(6) statistical section		
	(d)(7) pediatric use		
	(f) CRF and CRT		