General Considerations for FDA Reviewers Viewing an Electronic Table of Contents

1. Reviewers must have the capability to view document titles and their corresponding headings in the electronic table of contents. Specifically:

    - Reviewers must be able to view the electronic table of contents the same way they would view the table of contents in a paper or electronic submission.

    - The title of each document should be listed under the appropriate heading(s).

2. Reviewers must be able to access documents directly from the electronic table of contents instead of going to an external interface to locate and view the document.

3. Reviewers must be able to define their own view for the layout of the electronic table of contents. Layout choices should be by:

    - Modules (e.g., all modules, module 1 (administrative and labeling), module 2 (Summary), module 3 (Chemistry), module 4 (Pharm/tox), module 5 (Clinical), or

    - Discipline (e.g., chemistry, pharmtox, biopharm, micro, clinstat, inspector, advertising, other). For example, disciplines specific for chemists would include modules 1, 2 and 3. The disciplines specified for biopharm would include modules 1 and 2, and the relevant portion of module 5.

4. Reviewers must be able to define the types of documents displayed in the table of contents as follows:

    - List all documents, or

    - List current documents only (e.g., do not include replaced or withdrawn documents in the display).

5. Reviewers must be able to define the part of an application they would like displayed. Their choices should be as follows:

    - Display the entire application – this should be a cumulative table of contents for all documents provided in every submission to a specified application to date.

    - Display the original application with amendments – this should include the table of contents for the original submission and all relevant amendments.

- Display the supplement number and type with amendments (each one needs to be listed (see submission information below for details)) – this should be the table of contents for the specific supplement to a marketing application with all relevant amendments.

6. Reviewers must be able to access and view the metadata (descriptive information about the document) for each document, including:

    - All of the information about the document supplied in the XML files.

    - Information on the revision history of the selected document. For example, if a selected document has been appended by other documents, the reviewer must have the ability to access and view all of the documents that have been appended to the selected document.

    - File size of the document.

    - Additional visual cues to indicate whether the document has been replaced, appended or withdrawn, or replaces or appends another document (e.g., the document icon might be shaded in a specific way if the corresponding document has been replaced).

    - Additional visual cue to indicate the type of document (e.g., PDF, XML, XPT).

7. Reviewers must be aware of which application they are viewing on the screen. The system should display the following application information as follows:

    - Application—Application type, number, company, product names

      Example: IND 12,345 – T2020/Isotretinoin/Accutane – Roche
      Example: NDA 12-3454- Accutane (isotretinoin) - Roche

    - Submission information — submission information for INDs should include the following information:

Sequence number	Submission date	Admin information	Summary information	Quality information	Safety information	Efficacy information
0000	Dec-12-2002	x	x	x	x	x
0001	Dec-15-2002	x	-	x	-	-

- The submission layout should present the following information for INDs:

Sequence number	Submission date	Submission type	Summary	Quality	Safety	Efficacy
0000	Dec-12-2002	Original	x	x	x	x
0001	Dec-15-2002	• Amendment 01	-	x	-	-
0003	Dec-18-2002	• Amendment 02	x	x	x	x
0002	Dec-16-2002	Supplement 01 (efficacy)	x	x	x	x
0004	Dec-21-2002	• Amendment 01	-	x	-	-

- Submission information for NDA/ANDA/BLA applications should include the following information:

  - Original
  - Resubmission
  - Supplement by type ((efficacy, labeling, establishment description, SUPAC, CMC, other)
  - Annual report
  - Periodic safety report
  - Presubmission
  - General correspondence
  - Advertising
  - Amendment
  - Other

8. Reviewers must be able to use the electronic table of contents off line as follows:

   - Reviewers must be able to download documents from a submission to a local drive, generate the table of contents for the downloaded documents, and access the downloaded documents.

   - Reviewers must be able to update the downloaded submission with more recent submissions.

9. Reviewers must be able to search document information within and across applications; the search results should be displayed using the table of contents headings

10. Reviewers must be able to print selected documents; reviewers must be able to print these documents individually or as batch sets.

11. Reviewers must be able to capture the most recently accessed documents and then return to the most recent location.

12. Reviewers must be able to bookmark locations within the electronic table of contents for future access.

13. The application must be compliant with the 1986 Rehabilitation Act section 508 so that reviewers with disabilities can use the software to navigate the applications.

14. The applications must be compatible with Microsoft Internet Explorer version 5.0 or higher.