**Regulatory Guidance – Template Numbering**

Fifth and sixth level subheading numbering should be avoided within a document. Thus, the Artos templates are built with subheadings that do not include the module number within the numbering string. For more information on eCTD numbering please see:

• M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use Guidance for Industry: <https://www.fda.gov/files/drugs/published/M4-Organization-of-the-Common-Technical-Document-for-the-Registration-of-Pharmaceuticals-for-Human-Use-Guidance-for-Industry.pdf>

MEETING REQUEST – FORMAL MEETINGS BETWEEN THE FDA AND BIOSIMILAR BIOLOGICAL PRODUCT SPONSORS OR APPLICANTS

* 1. Product Name
  2. Application Number
  3. Proposed Proper Name (or Proper Name if Post-Licensure)
  4. The Structure
  5. The Reference Product Name
  6. The Proposed Indication(s) or Context of Product Development
  7. The Meeting Type
  8. Purpose of Meeting
  9. A List of the Specific Objectives/Outcomes the Requester Expects from the Meeting
  10. Proposed Agenda

|  |  |
| --- | --- |
| Topic | Estimated Duration |
|  |  |
|  |  |
|  |  |

* 1. List of Proposed Questions
     1. Chemistry, Manufacturing and Controls
     2. Nonclinical
     3. Clinical
     4. Electronic Submission
  2. List of Sponsor Attendees

|  |  |
| --- | --- |
| Name | Title |
|  |  |
|  |  |
|  |  |

* 1. List of FDA Staff, or Disciplines

|  |  |
| --- | --- |
| Name | Title |
|  |  |
|  |  |
|  |  |

* 1. Suggested Dates and Times
  2. Proposed Format of the Meeting