Guidance on Using this template

| Typographical Conventions | | |
| --- | --- | --- |
| Black Text | Text (mostly headings) that agency reviewers are expecting to see in your document, based on the ICH guidances and EMA guidelines. | |
| Red Text | General guidance and instructions to authors, taken from ICH guidances and EMA guidelines. Use this text to help you develop the appropriate content for your document. Can be turned on or off using the **Show or Hide Hidden Text** button on the StartingPoint toolbar. | |
| Highlighted Yellow Text | Sample Text - wording or tabular format suggested by Accenture, based on our experience and best practices. To use this text, remove highlighting and use, modify or replace as necessary. | |
| {Shaded Text in Curly Brackets} | Document Information field - press the **Document Information** button, replace default values with those required in your document, and click ‘Update’. | |
| **Helpful Word Tips** | | |
|  | | Ease of Use button: configures MS Word for ease of use with StartingPoint. Helps with:   * Keeping track of styles (sets the Style Area Pane in Draft view to 1”) * Keeping track of Document Information & caption fields (sets Field Shading to “Always”) * Ensuring Instructional Text appears when a template is first opened (sets Hidden Text to “On”) |
| **Helpful Toolbar Hints** | | |
|  | Most commonly used heading styles. Click once, enter heading text and click enter. Next line will automatically be in C-Body Text style. More styles are available in the regular MS Word Style menu.  Toggle Non Numbered Headings button: Click to display non-numbered headings toolbar. | |
|  | Appendix style button: Use to select Alphabetic or Numeric numbing for the appendices in the document. | |
|  | Regular body text and indented text buttons: Use for most text other than headings. | |
|  | Numbered, lettered and bulleted list buttons: Use these in preference to those on the regular MS Word toolbar, to ensure consistent formatting across all documents in your regulatory submission. | |
|  | Cross-reference button: Use to refer to tables, figures and sections. *Don’t* use regular MS Word command Insert\Reference\Cross-reference. | |
|  | Document Information button: Use to update Document Information fields in your document. | |
|  | Symbols and PK Symbols buttons: Click these buttons to hide or display toolbars of the most popular symbols known to render correctly to PDF. | |
|  | Paste Unformatted Text button: Use to paste text from other documents. **Note:** Do not use with tables. | |
|  | Hidden text buttons: Use to hide/show Instructional Text, and to delete it at document finalization. | |
|  | Toggle Draft / Layout View button: Toggles between Draft and Print Layout view | |
|  | Update all fields in a document: Use to update all areas on the document that contain field codes, such as a TOC or cross-reference. | |
|  | Document Validation button: Use to check your document for correct styles, fonts, margins, etc. | |
| **Document Finalization** | | |
| * Ensure all sample (yellow highlighted) text has been either converted to black text or deleted. * Update the TOC, LOT and LOF . Ensure all sections, tables and figures are correctly numbered.  * Use the Delete Hidden Text button to delete all hidden (instructional) text from your document. * Ensure all comments and track changes have been appropriately removed. * Run a Document Validation check to confirm all styles, formatting, margins, etc are correct. | | |

<<Insert Date>>

<<Insert Division Director’s Name>>, M.D., Director

<<Insert Division’s Name>>

Center for Drug Evaluation and Research

Attn: Document Control Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

**Re: NDA No. {NDA No.}**

**{Drug Name}**

**Original New Drug Application**

Dear Dr. <<*Insert Director’s Last Name*>>:

In accordance with Section 505(b) of the Federal Food Drug and Cosmetic Act and Section 314.50 of the United States Code of Federal Regulation, {Sponsor Name} is submitting an Initial New Drug Application for {Drug Name} for the indication of {Indication}.

<<If applicable, the following are possible discussion points:

Describe any agreements/commitments from pre-NDA Meeting;

Status of Tradename;

Orphan Drug Status;

User Fee Waiver;

Identification of the different drug names throughout the drug development program.>>

This IND is organized in accordance with the Agency’s Guidance for Industry, “Providing Regulatory Documents in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using eCTD Specifications (June 2008).” Attached, please find the electronic submission information.

The confidentiality of this submission, and all information contained herein, is claimed by {Sponsor Name} under all applicable laws and regulations. Disclosure of any such information is not authorized without the prior written authorization of {Sponsor Name}.

Any questions concerning this submission can be addressed to me at the following address <<insert address>>, or please contact me directly at <<insert phone number>> or alternatively via email at <<insert email address>>.

Sincerely,

<<*Insert Name*>>

<<*Insert Title*>>

**Electronic Submission Specifications**

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

**-or-**

All electronic files included in this submission are provided on a <<insert number>> CD-ROM or DVD and the electronic submission is approximately <<XX>> MB. All files were checked and verified to be free of viruses.

Complete the following tables with the applicable information

|  |  |
| --- | --- |
| Anti-Virus Program |  |
| **Program Version** |  |
| **Scan Engine Version** |  |
| **Virus Definition Date** |  |
| **Submission Size** |  |

The IT point of contact for this submission is:

|  |  |
| --- | --- |
| Name |  |
| **Phone Number** |  |
| **Email Address** |  |