

**SOPP 8101.1 Appendix 4
Template**

CBER Meeting Response Memorandum

Our Reference: *tracking # (IND, BLA, CRMTS, PTS etc)*

Application Division or Regulatory Management Staff Name

TODAY'S DATE: _____ **PAGES:** _____ **(Including Cover Sheet)**

TO:

FROM: POC _____

POC title

POC phone number: (Fax); (Voice)

SUBJECT: Summary of FDA Internal Meeting

PRODUCT:

We have completed our review of your information package for *(insert product name)* and are providing the following responses to the questions you posed in the package. Although we continue to reserve *(insert scheduled date and time for meeting)* for a *(choose one: telecom or face-to-face meeting)* with you regarding this product, if you find that our attached responses and advice are sufficiently clear and complete to obviate the need for further discussion, please inform us as soon as possible so that the meeting time may be cleared. Alternatively, if you have questions regarding specific responses or advice, please inform us so that the appropriate members of the review team can provide clarification during the reserved meeting time.

THANK YOU

(Insert Page Break)

Questions from the Sponsor/Applicant:

Discipline Title *(insert title for each discipline for which the sponsor is seeking guidance)*

- 1. State Sponsor/applicant question**
Insert CBER consensus response