Appendix 2 - Content of Review Memoranda for Management Review Package

Summaries of each of the below elements of the submission:

1. a description of the product and its intended use (e.g., identification of the serious or life-threatening disease or condition for which the product may be effective);
2. identification and an explanation of what unmet need(s) would be addressed by issuance of the EUA;
3. a description of the product's approval or clearance status, if any, under the FD&C Act or licensure status under the PHS Act, and whether the product is under an investigational application (e.g., whether the product is unapproved or whether it is approved but the EUA is for an unapproved use; whether an IND or IDE is in effect or is pending);
4. a list of each site where the product, if authorized, would be manufactured and the GMP status of the manufacturer;
5. identification of any approved alternative products, including their availability and adequacy for the proposed use (if known);
6. available safety and effectiveness information for the product;
7. a discussion of risks and benefits;
8. a description of the information for health care providers and recipients of the product, e.g., the "Fact Sheet"), and the feasibility of providing such information;
9. information on chemistry, manufacturing, and controls;
10. instructions for use; and,
11. proposed labeling (if applicable).