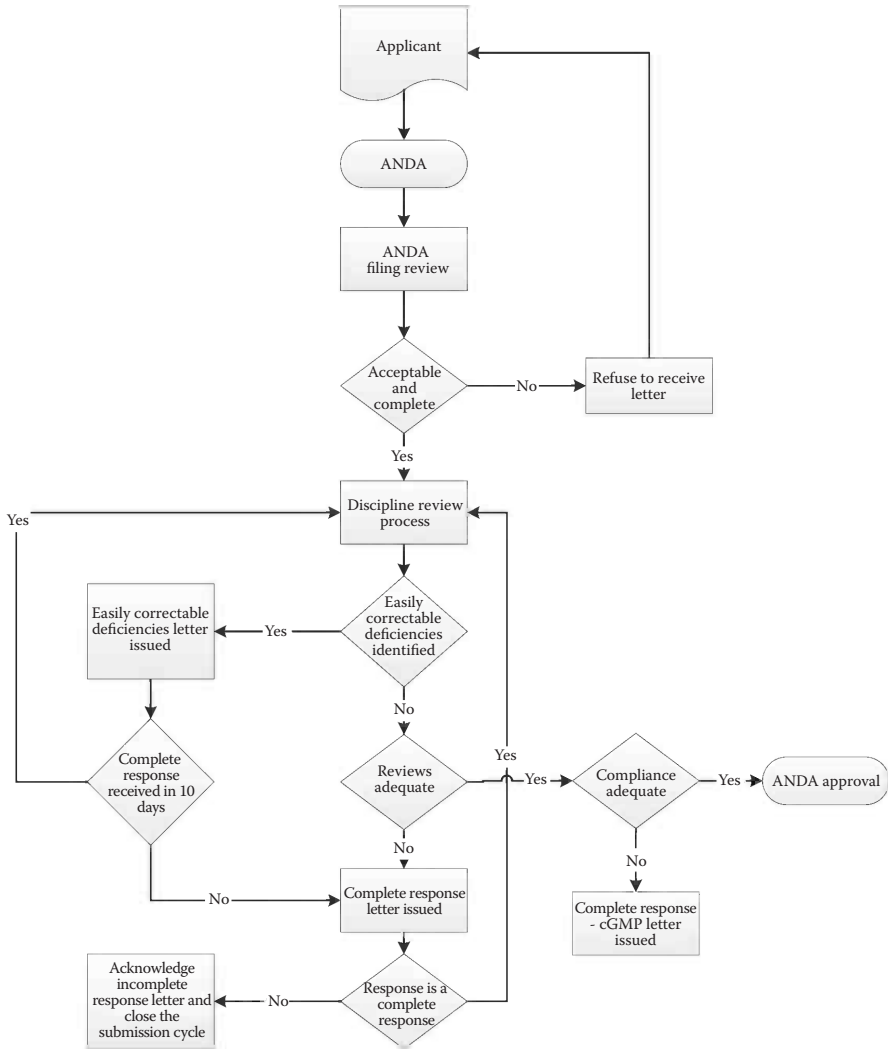


APPENDIX 9.A ANDA REVIEW PROCESS



- An ANDA is received by the OGD.
- Once an ANDA is found acceptable for filing, the discipline review process will begin.
- Throughout the discipline review process, easily correctable deficiencies (ECD) may be identified; if ECDs are issued, the ANDA applicant has 10 federal government business days to respond.
- Responses to ECD that are incomplete or partial will be incorporated in a Complete Response (CR) letter with all remaining deficiencies from all pending review disciplines.
- Once a CR letter is issued, the review cycle is considered closed.