OTC Local Anesthetic Cream - FDA Submission Guidance (NDA or Abbreviated NDA) Services Action Items

- Review and understand FDA requirements for NDAs and ANDAs.
- Assemble a multidisciplinary team (regulatory, clinical, quality).
- Prepare comprehensive clinical study reports and summaries.
- Develop a detailed regulatory submission timeline.
- Ensure all preclinical and clinical data are validated and formatted per FDA guidelines.
- Create a submission dossier that includes all required sections (e.g., Chemistry, Manufacturing, Controls).
- Conduct a gap analysis to identify missing information before submission.
- Establish a system for tracking submission progress and FDA communications.
- Prepare for potential FDA queries with a response strategy.
- Schedule and conduct internal reviews of the submission package.