

Project Case Summary
505(b)(2) NDA and MAA for Orally Disintegrating Tablet
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Client:	<i>Small U.S. start-up company specializing in acquiring, developing and marketing select pharmaceuticals</i>
FDA Reviewing Division:	<i>Division of Neuropharmacological Drug Products</i>
Project Profile:	<i>Orally Disintegrating Tablet</i>

1. Prepared Development Strategy
2. FDA pre-IND Meeting
 - a. Prepared and Submitted Meeting Request and Package
 - b. Prepared Team for and Participated in Meeting
3. IND Application
 - a. Managed overall compilation of IND, including templates, timelines, task lists, and project team
 - b. Prepared and QA-reviewed IND sections requested by client
 - c. Assembled and submitted IND
 - d. Prepared and submitted Amendments and Annual Reports
4. CMC
 - a. Advised in management of technical activities of drug product contract manufacturer (formulation development, pilot scale, clinical supply manufacture, commercial scale-up batches, validation)
 - b. Advised in batch record creation, analytical methods review, validation protocol development and review, validation report review
 - c. Performed CGMP audits
 - d. Provided regulatory strategy, contract manufacturer and testing solutions for Child Resistant packaging
5. Clinical
 - a. Managed Clinical Research Organization activities
6. 505(b)(2) NDA
 - a. Managed overall compilation of NDA, including templates, timelines, task lists, and project team
 - b. Prepared technical sections
 - c. Prepared draft labeling of drug product, including package insert, blister cards, and outer carton labels
 - d. Prepared labeling sections, including side-by-side comparison, and annotated labeling
 - e. QA review of the document in the NDA
 - f. Assembled and submitted 505(b)(2) NDA
 - g. Prepared and submitted Amendments, as needed
7. Post Approval Support
 - a. Prepared and submitted Annual Reports,
 - b. Prepared and submitted periodic and 15-day AE reports
 - c. Participated in product formulation change activities

- d. Prepared prior approval supplement for formulation changes
 - e. Provided bulk API, manufacturing, and packaging forecasts
 - f. Reviewed and approved commercial batch documentation for release to market
 - g. Reviewed and approved change control requests
 - h. Prepared and submitted DDMAC submissions
 - i. Maintained regulatory files and CMC documents
8. Ex-U.S. Submissions
- a. Planned meeting package and attended meetings with Canada, the Netherlands, and the UK
 - b. Participated in planning, provided technical details and prepared documents for MAA submission to Netherlands, the EU reference member country
 - c. Participated in strategic discussions and prepared response to questions to Netherlands Medicines Evaluation Board (MEB) regarding the MAA

Outcome:	<i>505(b)(2)NDA approved. MAA in progress.</i>
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