

Case Study 50: Pre-NDA meeting with FDA for 505(b)(2)



Client

A US based pharmaceutical company.

Products

New formulation of Metformin and new drug delivery technology

Product Categories

Small Molecule

Country of Interest

USA

Services Provided

- ✓ Submit a Type B Meeting Request for Pre-NDA meeting with FDA
- ✓ Preparation for Pre-NDA Meeting package with FDA
- ✓ Regulatory Strategy for 505 (b) 2
- ✓ Publishing BB in eCTD format

Key Highlights:

- ✓ Client benefited from GRP's strong regulatory experience with US FDA's 505(b)(2) applications
- ✓ Reduced risk, informed decisions, consultative approach with US FDA for regulatory success

Key Phrases:

505(b)(2) Regulatory Pathway, Drug Registration with FDA using 505 (b) 2, Regulatory strategy 505 (b) 2, Gap analysis for 505 (b) 2 for FDA.

Client Situation

The Client is a US based manufacturer of pharmaceutical products who had developed a new formulation for Metformin tablets with modified drug delivery technology. Client needed to understand the possibility of submitting NDA to US FDA using the 505 (b) 2 pathway in order to minimize development time and cost.



For additional information,
please contact us at
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GRP Solution

GRP has significant experience in obtaining FDA approvals using 505 (b)2 pathway for drugs with new formulations, combination drugs, new indications and new delivery technologies. GRP engaged with Client to identify a suitable strategy for registration using FDA's 505(b)(2) pathway based on available information. The entire project was executed three phases as outlined below.

1

Gap Analysis

- ✓ Perform gap analysis of the following information sent by client:
 - CMC information
 - Pharmacology
 - Toxicology
 - Clinical
 - Labeling
- ✓ Define the regulatory strategy for submitting NDA using 505 (b) 2 based on the outcome of gap analysis
- ✓ Discuss the RA strategy with clients and next steps

2

Pre-NDA Meeting Request

- ✓ Request Pre-NDA Type B meeting with FDA
- ✓ Preparation for Pre-NDA Meeting package for FDA that includes the following information:
 - An analysis of the current treatments used in US for diabetes.
 - Summaries of pharmacology, pharmacokinetics and toxicology studies
 - Proposed protocol design o Rational for the proposed study
 - Questions to FDA
- ✓ Publishing of Briefing Book

3

Support During FDA Meeting

- ✓ Prepare the client for the meeting with FDA
- ✓ Attend the FDA meeting with the client
- ✓ Prepare meeting minutes