

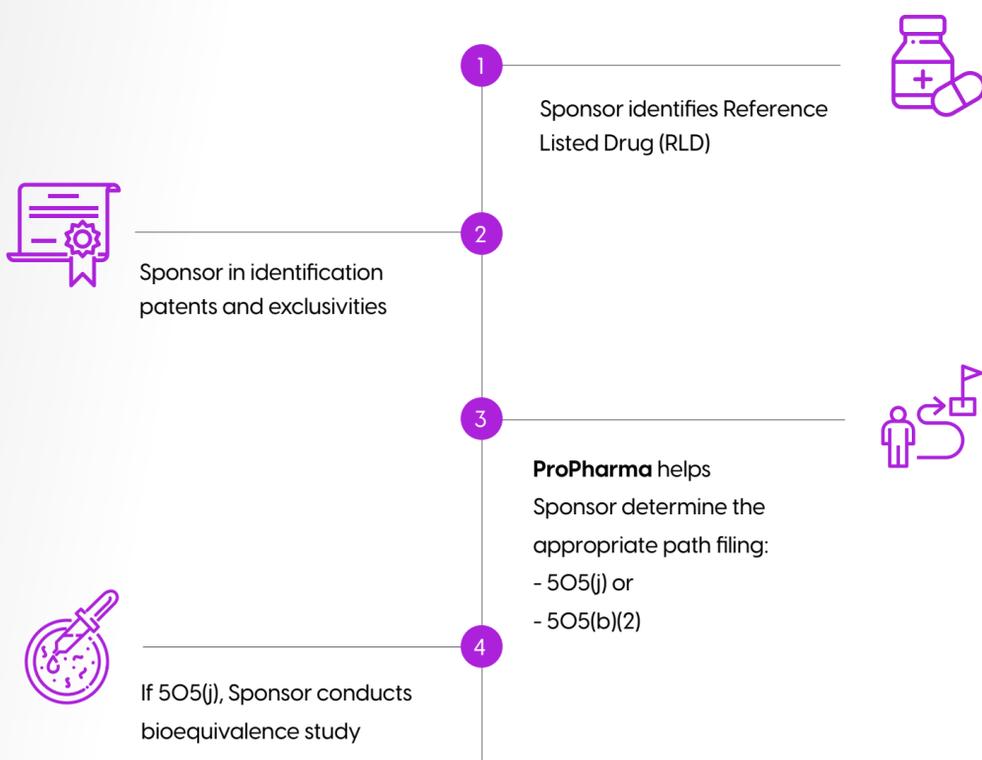
# How ProPharma Supports Clients Through The Generic Drug Application and Approval Process

## How does an ANDA Differ From an NDA?

- Abbreviated Application
- Typically, No Preclinical or Clinical Data Required
- Approval Based on Bioequivalence With Innovator Drug



## Pre-Filing Phase



## Is it a 505(j) or a 505(b)(2)?

(j) – same active ingredient, conditions of use, route of administration, dosage form, strength, and labeling (with certain permissible differences) as the RLD

(b)(2) – different active ingredient, condition of use, route of administration, dosage form, strength, or labeling than the RLD

## ProPharma

Supports clients in pre-filing activities, including:



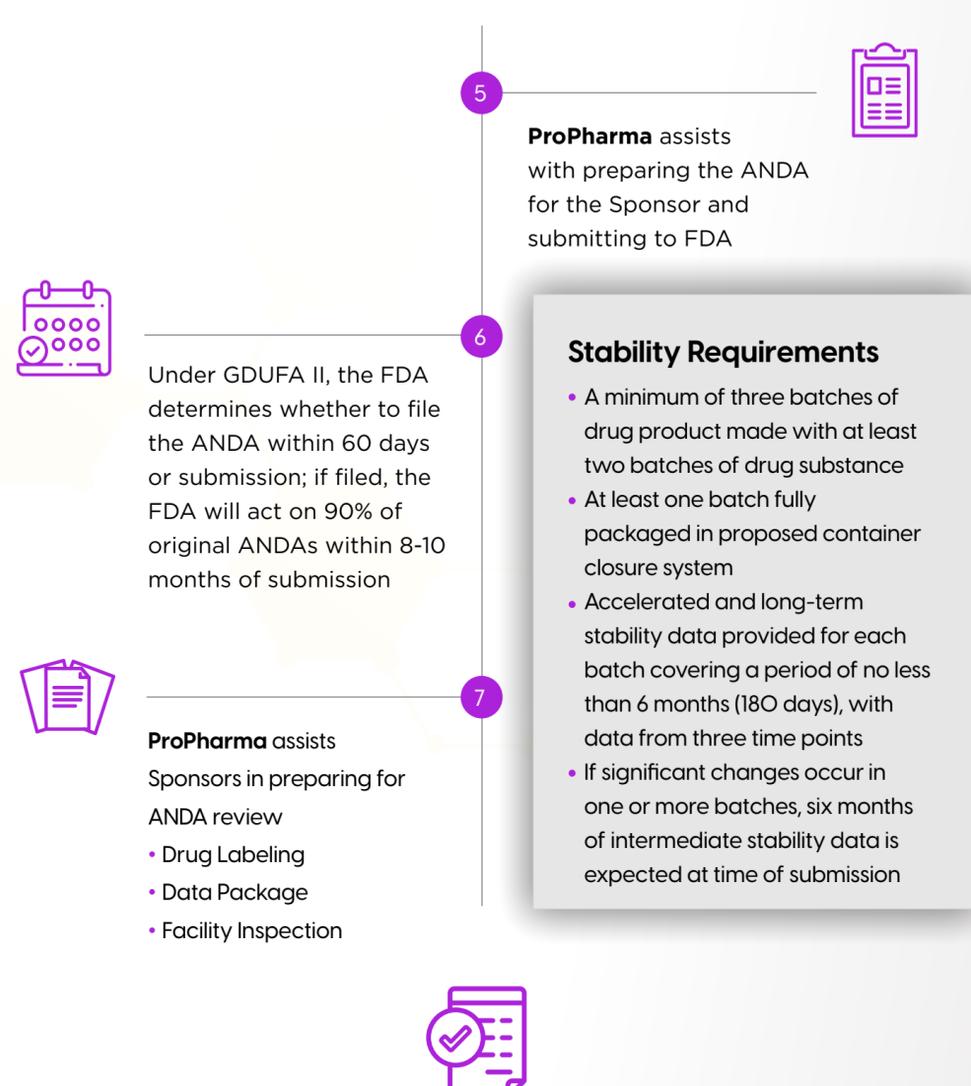
Controlled Correspondence



Pre-ANDA Meeting Requests



## Filing Phase



## Post-Approval



Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle

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