

How ProPharma Supports Clients Through The Generic Drug Application and

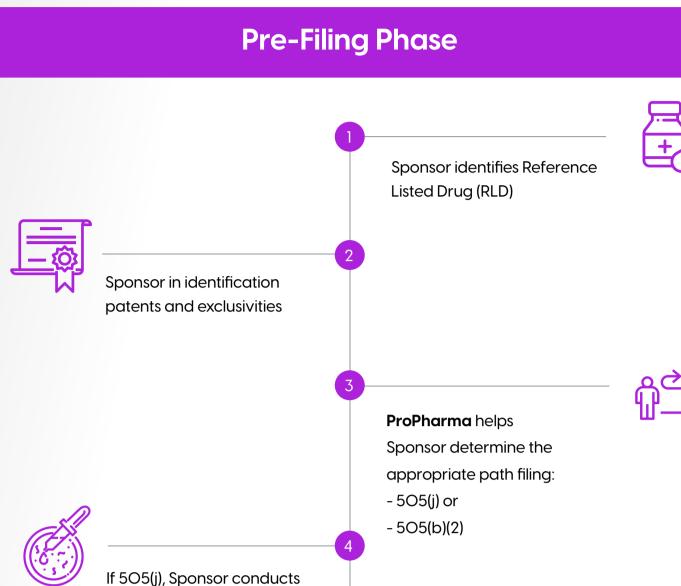
Approval Process



How does an ANDA Differ From an NDA?

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



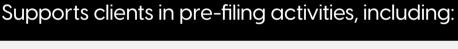


Is it a 505(j) or a 505(b)(2)?

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

strength, or labeling than the RLD

(b)(2) – dierent active ingredient, condition of use, route of administration, dosage form,



ProPharma



bioequivalence study

Pre-ANDA Meeting Requests

Controlled Correspondence





original ANDAs within 8-10 months of submission **ProPharma** assists Sponsors in preparing for

Under GDUFA II, the FDA

determines whether to file

the ANDA within 60 days

or submission; if filed, the

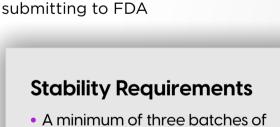
FDA will act on 90% of



 Data Package Facility Inspection

ANDA review

Drug Labeling



drug product made with at least

two batches of drug substance

ProPharma assists

for the Sponsor and

with preparing the ANDA

packaged in proposed container closure system Accelerated and long-term

stability data provided for each batch covering a period of no less

At least one batch fully

than 6 months (180 days), with data from three time points If significant changes occur in one or more batches, six months of intermediate stability data is

expected at time of submission



Post-Approval



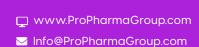
of the approved ANDA Annual Reports Supplements

- Periodic Adverse Drug **Experience Reports**
- (PADERs)

ProPharma can assist

with life-cycle management

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



product lifecycle