How ProPharma Group 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

1. Sponsor identifies Reference Listed Drug (RLD)
2. Sponsor in identification patents and exclusivities
3. **ProPharma Group** helps Sponsor determine the appropriate path filing:
   - 505(j) or
   - 505(b)(2)
4. If 505(j), Sponsor conducts bioequivalence study

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 Group

Supports clients in pre-filing activities, including:

- Controlled Correspondence
- Pre-ANDA Meeting Requests

Filing Phase

5. **ProPharma Group** assists with preparing the ANDA for the Sponsor and submitting to FDA
6. 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 original ANDAs within 8-10 months of submission
7. **ProPharma Group** assists Sponsors in preparing for ANDA review
   - Drug Labeling
   - Data Package
   - Facility Inspection

Stability Requirements

- A minimum of three batches of drug product made with at least two batches of drug substance
- At least one batch fully packaged in proposed container closure system
- Accelerated and long-term stability data provided for each batch covering a period of no less 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

8. **ProPharma Group** can assist with life-cycle management of the approved ANDA
   - Annual Reports
   - Supplements
   - Periodic Adverse Drug Experience Reports (PADERs)

SCIENCE MINDS OVER REGULATORY MATTERS.

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

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