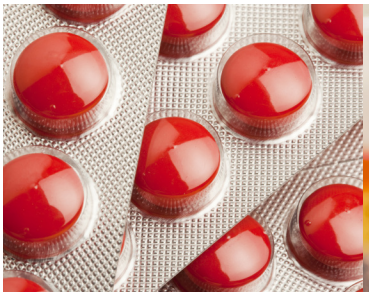

Cooley

Guide to Successful Drug Naming

Drug names in the US and foreign countries must navigate a complex dual-track legal process, including approval by trademark offices (e.g., U.S. Patent and Trademark Office (USPTO)) and drug regulatory agencies (e.g., Food & Drug Administration (FDA)). **Name creation to final approval can take more than three years** as the process has many pitfalls that can impact your ability to successfully launch a branded drug. Early and thorough planning is imperative. Our checklist will guide you through the recommended steps in each phase of the process.

Benchmark	Action item
Company formation	Establish the company brand first: ☐ Conduct trademark search on – and protect – company name and logo design ☐ Register domains and social media handles for company name
Post phase I	Consider creating early brand assets: ☐ Develop and search *clinical trial brands* for Phase II & III trials ☐ Develop and search *project codes* and unofficial names
Early phase II	Substantive work begins: ☐ Obtain *generic names* from World Health Organization and United States Adopted Names Council ☐ Engage drug naming agency to develop potential name candidates
Mid phase II	The quest to find winners: ☐ Internally review and select preferred names from slate of candidates proposed by naming agency ☐ Conduct *knockout searches* to identify and eliminate high risk names among the preferred names ☐ Conduct more *thorough searches* (US and internationally) on the surviving names ☐ Register domains and social media handles for top-choice names ☐ Test focus groups and further refine top-choice names ☐ File initial trademark applications for slate of preferred names at USPTO ☐ Conduct *drug safety testing* on slate of preferred names ☐ File *priority foreign applications* (within 6 months of the initial filing) for top-choice names ☐ Prepare *specimens of use* for top name
Post phase II	Survival of the fittest name: ☐ Submit top two names to FDA/European Medicines Agency (EMA) for *conditional approval* ☐ Navigate *trademark conflicts* ☐ *Watch* third-party filings to stop potentially conflicting names
NDA	Final stretch: ☐ Submit top two viable names to FDA/EMA ☐ Develop, search and protect *product logo*, tagline and other brand assets
Final step	**Commercial launch of successfully named drug**

**italicized terms are defined on back*

Key terms and tips

Clinical trial brand: More companies are choosing to brand their clinical trials, which is the first opportunity to build memorable perceptions, awareness and familiarity for your future product.

Conditional approval: The FDA permits applicants to submit the top two candidate names for a preliminary assessment following conclusion of Phase II trials. The final drug name approval, however, will not be issued until 90 days prior to the final FDA drug approval date.

Drug safety testing: Conducted by specialized agencies, drug safety tests evaluate a proposed name under certain FDA name review procedures to assess potential drug naming errors that may cause harm to health or safety.

Generic name: Scientific name that identifies the pharmacological traits of the drug, known as an INN (International Nonproprietary Name) by the World Health Organization and USAN (United States Adopted Names) by the USAN Council. You must obtain an approved generic name prior to submitting a New Drug Application/ Biologics License Application.

Knockout search: A streamlined initial trademark search to identify dead-end marks to eliminate from further consideration.

Priority foreign applications: Trademark rights are limited on a per-country basis and **usually granted in order of earliest filing date**. Foreign trademark applications filed within six months of the initial filing will be given the same "priority" as if filed concurrently with the initial filing. After the six-month period, subsequent applications will be treated on an as-filed basis.

Product logo: A design element for your drug is important for identity and consistency, as the actual drug name may differ (e.g., translated) in some countries.

Project code: Early internal reference for a compound (e.g., ABC-001). Before using the project code publicly, you should conduct a trademark search to avoid incurring potential infringement risks.

Specimen of use: The USPTO requires evidence of use of the trademark before issuing registration. For drug names, acceptable specimens include proof of usage on product labels or packaging for out-of-state clinical trial shipments.

Trademark conflicts: Trademark conflicts typically involve confusingly similar marks owned by a third-party in the relevant field, and may arise via: 1) local trademark offices that refuse your application; 2) third parties that oppose the registration of your trademark application; or 3) third-party demand letters.

Trademark search: Trademark searches assess the availability of the mark for use/registration and can include results from FDA databases, which contributes to the FDA's final decision on the proposed name.

Watch: A monitoring service to alert you to third-party trademark filings for similar names, so you can timely oppose such applications.

Rule of thumb: Start the **generic naming** process immediately following Phase I trials. Start the **brand naming** process by two years before NDA submission or three years before commercialization – whichever is earlier.

Cooley has one of the largest full-service trademark groups found in any of the Am Law 50 law firms, with 30+ lawyers and a dozen paralegals across the US and Europe. We have significant experience advising pharmaceutical and medical device clients on a full spectrum of issues arising across all stages of development, commercialization, post-marketing and loss of exclusivity. Among other services, we advise on the complex process of selecting, clearing, protecting and obtaining regulatory approval for drug and device names; build a business-friendly brand strategy to maximize marketplace advantages and protection during the product lifespan; and represent clients in disputes and enforcement matters worldwide.