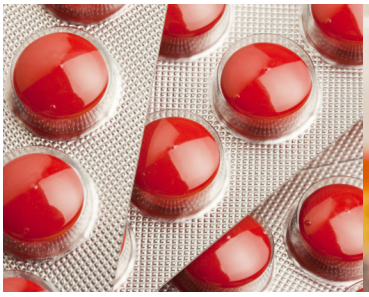

Cooley

Navigating the Processes and Pitfalls of Drug Naming

Drug naming is more lengthy, complex and risky than it appears.

The two main goals of selecting a drug name are satisfying marketing objectives and obtaining legal approvals. On the marketing front, the brand name should be memorable, impactful, able to function as a global brand and sufficiently distinctive to stand out in the marketplace. On the legal front, most countries have a dual-track system whereby the proposed name must obtain trademark approval (e.g., by the US Patent and Trademark Office (USPTO)), as well as drug marketing approval (e.g., by the Food & Drug Administration (FDA)). Clearing these hurdles in each relevant country can be a formidable challenge.

In the US, the two agencies responsible for legal approvals of drug names are the USPTO and the FDA. At their core, both agencies agree that you cannot use a drug name that is confusingly similar to any other existing drug name. Otherwise, the two processes are governed by separate government agencies with different procedures that aim to accomplish different objectives (i.e., trademark infringement v. drug safety). They also follow different timelines, confidentiality rules, priority recognition, and review different datasets – and recognize no reciprocity with each other. Below is a summary of procedures at each agency.

The USPTO process

Most trademark applications for drug names are filed on an intent-to-use basis, before the product is commercialized. Once filed at the USPTO, the process largely falls into three stages:

1. **Examination**. During the first stage, a USPTO examining attorney will search the US trademark register to identify any identical or closely similar trademarks that already exist in the field of pharmaceuticals or other related fields (e.g., nutritional supplements). If the examiner finds a prior filing that he believes is confusingly similar to yours, he will refuse registration of your proposed name. The examiner must withdraw all refusals before your application can continue to proceed toward registration.

Every drug has three distinct names:

1. Chemical name – A long complicated name that specifies the molecular structure of the compound. It is typically used only by manufacturers and researchers (e.g., N-(4-hydroxyphenyl) acetamide).
2. Generic name – Also called the “non-proprietary name,” it specifies the pharmacological traits of the drug. This is the name used to refer to the underlying compound regardless of the developer. Generic drug manufacturers can use this name after the patent expires on the reference drug (e.g., acetaminophen, paracetamol). Generic names must be approved by the World Health Organization and United States Adopted Names Council.
3. Proprietary name – The name that specifies the brand (and therefore the specific developer) of the drug. The FDA must review and approve proposed proprietary names prior to marketing the drug (e.g., Tylenol).

2. **Publication/opposition**. If the proposed name survives examination, it will be “published” in a public document so that any interested third parties can object in a proceeding called an “opposition.” You must resolve all oppositions before your drug name application can continue to proceed toward registration.
3. **Statement of use**. Once the proposed name survives the publication/opposition stage, the adversarial part of the trademark process is over. In the last stage, you must show proof of use of the drug name – either in a clinical trial or in the marketplace – and satisfy other technicalities (in a submission called “Statement of Use”) in order for the registration to issue.

The best way to mitigate the risk of conflict at the USPTO is to conduct an early and thorough trademark clearance search on the proposed drug name, as well as several backup names, with an experienced trademark attorney.

The FDA process

You can request the FDA to preliminarily review your top two proposed drug names following Phase II clinical trials and provide conditional approval, if possible. The FDA will conduct another review of the proposed drug name at the time of the NDA/BLA submission and provide another conditional approval, if applicable. However, the FDA will not issue a final approval on the proposed name until 90 days before the anticipated date of final drug approval. It is important to note that you may receive two conditional approvals and still receive a final refusal.

At the FDA, the review process falls into four stages:

1. **Prescreening review**. At the prescreening stage, the FDA checks for obvious dead ends, like certain abbreviations that are prohibited from being incorporated into drug names.
2. **Misleading/error-prone review**. During this stage, the FDA examines the proposed name for traits that are highly misleading or prone to error. These can include components like numerals.
3. **Misbranding review**. The FDA assesses the messaging conveyed by the proposed name in the misbranding review. The proposed name must not be overly promotional or imply unique efficacy (e.g., “MiracleCure”).
4. **Look-Alike Sound-Alike (LASA) safety review**. In the LASA review, the FDA analyzes the proposed name for confusing similarity with other pending or approved drug names. The FDA relies on various tests and data to assess confusing similarity including:
    - Name simulation studies wherein volunteers test various prescription scenarios with the proposed name
    - Phonetic and Orthographic Computer Analysis (POCA) algorithm, which compares the candidate name with others in several databases and assesses a numeric value representing the degree of similarity to each reference
    - Reports of medication error data from marketplace confusion due to nomenclature issues among existing drugs

The results of the FDA review are difficult to predict, so you should submit your proposed names to the FDA for conditional approval as early as possible. This gives you the advantage of obtaining an “early read” on your top choice name(s) by the FDA.

Best practices

The USPTO and FDA processes are both tricky and time-consuming procedures. The importance of starting the process early and having viable backup names cannot be overstated. You should consult with your trademark and regulatory counsel on the best strategy to prepare candidate drug names in time for a smooth product launch.

Each year, the FDA reviews hundreds of proposed proprietary name submissions. Historically, the FDA rejection rates for these have ranged from 26-59%, which is why every applicant should have viable backup names prepared.

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.