



FDA Approval of Trademarks

As consumers become exposed to more and more pharmaceutical brand names, the role of the US Food and Drug Administration (FDA) in reducing brand name confusion takes on an ever-growing importance. The last thing a drug maker wants to do is invest time and effort developing a brand name that is a strong trademark but cannot pass muster at the FDA.

Even successful registration of a drug name at the US Patent and Trademark Office (PTO) does not guarantee FDA approval. There are steps you can take to facilitate the process and maximize the likelihood of a successful outcome.

This guide provides background information about how the FDA reviews drug names. It is intended to give drug makers insight into how the FDA will scrutinize drug brand names, so that manufacturers might choose names that will gain FDA approval.

Additional information is available in the [FDA's May, 2014 draft guidance document](#) on "best practices" for developing pharmaceutical trademarks.

Rationale for FDA Involvement: Preventing Medication Errors

There are 3 billion retail prescriptions sold annually in the United States. Among those prescriptions, there are an estimated 1.3 million injuries from medication errors each year.

About 12.5 percent of medication errors are attributed to confusion by health care professionals between drug brand names.

The FDA has a mandate to help prevent medication errors caused when two drugs have confusingly similar names. The FDA's Division of Medication Error Prevention and Analysis (DMEPA) is responsible for reviewing drug trademarks both before and after marketing. In reviewing names, the FDA considers whether a drug name will be confusing not only for consumers, but also for physicians, pharmacists, and nurses.

DMEPA reviews all proposed names for confusing similarity to the names of other drugs or drug ingredients, including both trademarks and "established" or generic names. DMEPA typically rejects about one-third of all names reviewed. Some of the issues DMEPA hopes to avoid include:

- Names that suggest potentially exaggerated efficacy claims. For example, the hair growth product known as ROGAINE in the United States is known as REGAINE throughout the rest of the world—the FDA would not approve REGAINE, since the product does not work for everyone;
- Names that could lead to erroneous prescriptions (e.g., wrong drug or dosage);

- And names that look or sound confusingly similar to other drug names. For example, while CELEBREX is an oral pain reliever, CEREBYX is an injectable drug to prevent seizures, and CELEXA is an oral antidepressant.

For a company seeking to introduce a new drug, DMEPA rejection can substantially increase time to market and threaten competitive advantage. It therefore makes sense to understand the FDA's perspective and select names with both the FDA and the PTO in mind.

FDA and PTO Timing/Perspectives Differ

A drug name can be registered as a trademark in advance of its approval by the FDA. An application for registration at the PTO can be based on "intent to use" a trademark or use of the mark in clinical trials. Unfortunately, whether or not the PTO registers a trademark has no bearing on FDA approval.

Avoiding Names the FDA Will Consider "Misleading"

Simple precautions can reduce the risk that a name will be found misleading:

- Avoid names referring to an inactive ingredient in a way that suggests effectiveness.
- Avoid incorporating generic stems in the stem position.
- Avoid names implying unique effectiveness (e.g., WONDER or MIRACLE GROW).
- Avoid using terms that imply maximum strength, such as "Ultra," "Max," "Pro," or "Super."
- Avoid "recycling" the trademark of a discontinued product.

Avoiding Names the FDA Will Consider at Risk for Medication Errors

Similar precautions can reduce the risks of choosing a name the FDA will consider prone to potential medication errors:

- Avoid names containing numbers that might be misinterpreted. Some pharmacists interpreted "Percocet 5" to mean five tablets per dose.
- Avoid letter prefixes, suffixes, and abbreviations that may have different meanings in the medical field—for example, BID, which means twice daily to pharmacists.

In general, the FDA gives greater scrutiny to the names of prescription drugs than those of over-the-counter drugs. Illegible handwriting on written prescriptions and inattention to pronunciation on phone orders can lead to pharmacy errors. "XL" in a drug name may sound like "SL," which indicates "sublingual" to pharmacists. With over-the-counter drugs, prefixes and suffixes are viewed directly by consumers, so there is no risk of misinterpretation by pharmacists. As a result, the FDA allowed TAGAMET HB for "Heartburn" and PEPCID AC for "Acid Control."

The potential consequences of a medication error are also factors in the FDA assessment. The more severe the potential consequences, the more stringent the review.

Avoiding Names the FDA Will Consider Confusingly Similar to Other Drug Trademarks

The FDA regularly tests drug names by using approximately 100 volunteers inside the organization as an aid to determining whether names are confusingly similar. These tests have yielded the following guidelines for avoiding names that might be confused with other existing trademarks:

- Consider the sound of the name when spoken, as if recording a verbal prescription into a voicemail system.

Example: ZANTAC/XANAX

- Consider the appearance of names as printed (CELEBREX/CELEXA), knowing that the FDA may use computer technology to detect spelling and phonetic similarities.
- Consider the appearance of a name as written by a physician. The FDA believes that the first letters of a drug name are typically written by physicians with more care than the remaining letters; as a result, it gives preference to names that can withstand this tendency.

Other considerations:

- The Rx status of the two products being compared (prescription drugs are less likely to be confused with OTC drugs)
- Marks that draw too heavily on the generic name of another drug
- Similarity with a company's own drug names (many pharmacies arrange drugs by manufacturer.)

Confusion of a different sort can arise when a company uses multiple trademarks for two of its products that have the same active ingredient. The FDA discourages this, since it may increase the risk of overdose. An exception may be made where there might be a stigma associated with one drug, such as PROZAC and SARAFEM for fluoxetine.

FDA Review of Trademarks for Biologics

Trademarks for non-therapeutic biologics, such as vaccines, are reviewed by a different FDA branch—the Advertising, Promotion, and Labeling Branch of the FDA's Center for Biologics Evaluation and Research (CBER). CBER has issued its "Standard Operating Procedures and Policies" for evaluating trademarks. In general, the CBER process is similar to the DMEPA process, with the additional provision that CBER discourages multiple trademarks for the same drug used for different indications.

Over the Counter Drug Products

When a product goes from prescription to over-the-counter, use of the same trademark may be acceptable if there is no change in indications, dosing, or strength. However, if the OTC and Rx versions are not identical, the FDA believes it "might be appropriate" to market the OTC product under a different or modified trademark.

The FDA will review a proposed trademark for an OTC drug that will be marketed pursuant to a New Drug Application or Abbreviated New Drug Application. However, many OTC drugs are marketed under an FDA monograph and are not individually scrutinized by the FDA. For these, the FDA still recommends that the trademarks be evaluated by the sponsor for safety considerations.

Brand Name Extensions

Trademark & Copyright

The use of brand name “extensions” (also known as family marks or umbrella names) are evaluated by the FDA on a case-by-case basis, considering whether the products share at least one common active ingredient, are differentiated by labeling, and have appropriate modifiers. The FDA will also evaluate on a case-by-case basis the use of different trademarks by the same manufacturer for products that contain the same active ingredient but for different indications.

Navigating the DMEPA Review Process

When requesting DMEPA approval for a proposed drug name, a drug maker must submit two (and only two) proposed drug names, in order of preference. If the first is rejected, DMEPA will evaluate the second. The drug maker must also submit the proposed package labeling, including both inserts and outer labeling, and any studies or data evaluating the proposed mark for potential medication error.

The review of a proposed name submitted during the investigational phase must be completed and communicated to the sponsor within 180 days, as opposed to 90 days for a request for review submitted with an application for a new drug or therapeutic biologic. Names that pass receive “tentative approval,” and a second evaluation will be initiated 90 days prior to final approval of the drug or biologic. During that second evaluation, DMEPA will also compare the proposed name with drug names that have been approved since the initial evaluation.

The FDA’s May 2014 draft guidance contains detailed descriptions of how the FDA conducts – and how sponsors should conduct -- name simulation studies to try to gauge how likely any given name will cause end user error based on phonetic, spelling, and orthographic similarities. Although sponsors are not required to submit their own studies, the FDA states that more comprehensive simulation studies “would be useful.”

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Post Marketing Surveillance

Even after a drug name has been approved, DMEPA monitors reports of problems with marketed drugs and can order changes in drug names it has approved. Some examples: LOSEC was changed to PRILOSEC after reports of confusion between LOSEC and LASIX. PEDIAPROFEN was changed to CHILDREN'S MOTRIN after reports that it had been confused with PEDIAPRED. And after reports that LEVOXINE was being confused with LANOXIN, it was changed to LEVOXYL.

Sometimes the FDA simply orders changes in labeling to eliminate confusion, rather than a complete name change. These changes may include changing the mix of upper- and lower-case letters, as well as special shading and distinctive colors. One example: new labeling to distinguish LamICTAL (an epilepsy drug) from LamISIL (an antifungal pill).

Recommendations to Facilitate FDA Approval of Drug Names

Drug makers should request DMEPA review early in the drug approval process.

Requests may be submitted at the end of Phase II of clinical trials.

Get PTO approval as early as possible by filing an "intent to use" trademark application.

Consult trademark and regulatory counsel to help minimize the risks.

Fish & Richardson advises many clients in the pharmaceutical area. In addition to assisting with obtaining registration of trademarks at the PTO and approval by the FDA, we advise on the process for obtaining generic names for new pharmaceutical compounds. We have also participated on the Pharmaceutical Subcommittee of the International Trademark Association and regularly attend conferences held by the Pharmaceutical Trademark Group

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