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Make "No Untitled Letters" Your New Year's Resolution for 2025

The new year provides new opportunities to make good choices–to stop scrolling, to get more exercise and to eat more vegetables, just to name a few. For pharmaceutical company leaders, there's another resolution you need to add to your list: to avoid receiving an untitled letter from the FDA in 2025.

Let's take a look at what untitled letters are and steps you can take to avoid receiving one.

What is an Untitled Letter?

The FDA's Center for Drug Evaluation and Research (CDER) issues several types of regulatory action letters. An "Untitled Letter", issued by Office of Prescription Drug Promotion (OPDP) within CDER, notifies a pharmaceutical company that a claim or claims it's making in its marketing materials violates the FDA Cosmetic Act, causing the company to not be in compliance with FDA regulations.

The untitled letter gives the company a chance to address the issue(s) by changing or removing the claim or claims. If the violation isn't corrected, the FDA will issue what's called a "warning letter," which is much more serious and could result in enforcement action.

Why should a company avoid receiving an Untitled Letter?

In short, receiving an untitled letter isn't good. Here are the main reasons why you and your company should avoid it:

- **Reputational damage:** An untitled letter is made public (see here on the FDA website), which means that healthcare providers, competitors, investors, partners and customers can see that your company isn't in compliance, which could potentially impact your relationships and financial stability.
- **Added costs:** Addressing the issues raised in an untitled letter often requires significant resources to pull materials from the market, update processes, and invest in additional training and external experts.
- **Increased scrutiny:** Once you're on the FDA's radar, future submissions for all of your brands may face more intense examination, which could slow down approvals and increase the time to market.

- **Risk of a formal warning letter**: If the issues raised in an untitled letter aren't addressed, that could lead to a warning letter or regulatory meeting, which could severely disrupt your operations.

If you do receive an untitled letter, it's critical that it's taken seriously and responded to promptly, in order to maintain your regulatory standing with the FDA.

How can you minimize your risk of receiving an untitled letter?

While the risk of receiving an untitled letter is never 0%, there are a few practices and processes your company should have in place to reduce the risk of non-compliance:

- **Foster cross-functional collaboration**: Ensure close alignment between your creative, marketing, legal, and regulatory teams by encouraging early and consistent communication.
- **Track regulatory changes**: Make it a priority to stay on top of changes to FDA regulations and adjust your processes as needed.
- **Implement quality control processes**: Ensure all claims made are substantiated and catch errors before they become compliance issues by putting enforceable, specific quality checks in place.
- **Build a culture of compliance**: Invest in training for your staff to ensure everyone understands their role in maintaining compliance.
- **Keep claims and documentation up-to-date**: Regularly review and update claims and documentation to reflect the latest regulatory requirements and product and competitor data.

Meet Revisto: Your partner in compliance

Even with the best practices and processes in place, managing compliance can be overwhelming. That's where Revisto comes in. Revisto harnesses the power of AI to streamline the MLR (Medical, Legal, and Regulatory) review process, making it faster and more efficient—without sacrificing quality or compliance.

With Revisto, you can identify and address issues early in the process, automate repetitive review tasks, improve quality of reviews, and create a transparent process that's easy for all stakeholders to follow. The result? Fewer errors and faster reviews, which significantly reduces your risk of receiving an untitled letter.

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Start 2025 off right. See how Revisto can help you keep your New Year's resolution to *not* receive an untitled letter by requesting a demo today.