

Advertising Compliance for Medical Devices: FTC and FDA Requirements

May 1, 2025

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The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) finely regulate the promotion compliance of medical devices—both in terms of the claims made and in the manner of their making. The upshot is that promotional claims about medical devices, including advertising, must be truthful and not misleading. To achieve this, the FDA and the FTC have established a series of very clear guidelines, and they have also set forth some basic, mostly “common sense” rules that any entity promoting a medical device would be wise to follow. This document is your essential guide to, and entryway into, the world of promotional compliance for medical devices.

Understanding FDA Regulations for Medical Device Labeling and Promotional Claims:

The Food and Drug Administration supervises the medical device promotional world, ensuring that claims made therein are truthful and based on solid evidence. They cover a lot of ground. The world of medical devices is not a small one, with hundreds of thousands of individual items that need to be carefully and clearly labeled. “Labeling” is a gigantic umbrella that covers any and all materials used to explain or promote the device. That means everything from brochures to website content to instructions. For a look at their comprehensive requirement list, hit up their webpage.

Scientific evidence must back medical claims. If a device manufacturer claims that the device can diagnose or treat a condition, there must be clinical data to back this up. Promoting a device for unapproved or off-label use is prohibited and can lead to enforcement actions.

For example, a developer encountered FDA fines for offering unsupported therapeutic representations about a wearable device. Once the firm fixed its labeling to drop these representations, it was able to get back on track and avoid further action. Find additional information about device labeling from the FDA at <https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling>.

Adhering to FTC Truth-in-Advertising Standards for Medical Devices:

Ensuring the truth in advertising is the main mission of the FTC, especially when it comes to advertising for medical devices. The statements made in the promotional purview must be clear, and more importantly, they must be substantiated. This means that when a device is being promoted, the claims that are made cannot be misleading or exaggerated in any way. Furthermore, there can be no deceptive language, and absolutely no omissions that might lead the consumer to think something different than what’s actually true.

Claims related to health necessitate a great deal of proof—usually clinical trials or large-scale scientific studies. When it comes to using a person to represent a product (i.e., endorsements), the FTC requires that what is said be an accurate representation of the typical user’s experience. Also, if a person is being used to represent a product, and that person is being paid, the

audience must be told so. A medical device company learned this lesson the hard way not too long ago. Visit <https://www.ftc.gov/business-guidance/resources/advertising-faqs-guide-small-business> for additional details.

Navigating Social Media and Digital Advertising Compliance:

When it comes to using digital platforms and social media to promote medical devices, there are defined compliance risks to consider. The FDA and FTC both have a hand in the regulation of these devices, but the FTC claims primary authority over the type of promotional speech (and the speakers) used in these venues.

Mandatory disclosures that go along with related claims should not be hard to find. They should be right there in plain view. To see what the FTC requires, rule-wise, you should look up their endorsement guides.

The same standards of truth and substantiation that apply to traditional advertising should also apply to social media posts. When influencers and affiliates promote medical devices on social media, they must ensure that their endorsements are in line with Federal Trade Commission (FTC) guidelines. This was not always the case, as evidenced by a recent revision of fitness device company social media influencer partnerships. The company in question now mandates that its partners include a clear and unmistakable disclosure of the kind of relationship they have with the company (in this case, that they are paid to promote the company's devices). Detailed FTC disclosure requirements can be found at <https://www.ftc.gov/business-guidance/resources/ftcs-endorsement-guides>.

Conducting Regular Compliance Audits and Staff Training:

Regular audits of marketing materials and thorough training of marketing personnel are critical to ensure compliance with the FDA and FTC. Promotions of all kinds must meet the standards set by these two agencies. Audits should encompass all promotional content, including digital media and printed materials—to guarantee compliance.

Regular training in labeling rules, claim substantiation, and the standards of honesty in advertising should be received by the marketing teams. When audits find compliance issues, companies must take immediate and corrective actions. A medical device manufacturer has successfully implemented an advertising audit and progressed to a level of compliance in their external communication. They are a case study in being better safe than sorry when it comes to the truth in advertising. Guidance on this topic can be found on the Federal Trade Commission's website.

Common Legal Risks and Penalties for Non-Compliance:

The FDA and FTC mandate how advertising should be done in the supplement industry, and they make it very clear which ways are not acceptable. They require actual science to back up what is said in an advertisement. They do this to ensure that consumers are not being misled. They also want to make sure that defendants in lawsuits do not have "but the supplement told me to take it" as a defense.

Compliance with FDA and FTC regulations is crucial for medical device manufacturers to avoid penalties and enhance consumer trust. Companies can achieve compliant advertising by substantiating claims, ensuring clear digital disclosures, and regularly auditing advertising practices.