



AMERICAN OPTOMETRIC ASSOCIATION

Understanding FDA Approval and Clearance and the Impact on Optometry Advertising



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Off-Label Marketing and Advertising is Illegal

It is common for doctors of optometry and other physicians to use a Food & Drug Administration (FDA)-approved drug or medical device differently than what the FDA approved the drug or medical device for. This is known as off-label use and is permitted in the context of diagnosing and treating our patients. An example is prescribing a steroid eye drop for symptoms of dry eyes when the FDA approval for the steroid is only post-operative inflammation. The education, training and experience of the optometrist allows for off-label treatment of patients.

However, it is illegal to advertise or market off-label treatments for drugs or medical devices for purposes for which the drug or medical device is not specifically approved. This is known as off-label marketing. To be clear, off-label diagnosis and treatment by a doctor of optometry is legal but off-label marketing and advertising of drugs and medical devices IS NOT. It is illegal to promote or advertise the use of a drug or medical device for anything other than its FDA approved use. An example is promoting (advertising) on social media the use a medical device to treat “dry eyes” if the medical device does not have that approval. Your marketing and advertising should be consistent ONLY with the verbiage of the FDA approval for that medical device.

FDA Approval vs. FDA Clearance

When evaluating medical devices, it is also important for doctors of optometry to understand the FDA’s various regulatory requirements for device manufacturers. According to the perceived risk of using a particular medical device, that device is then classified as Class I, II or III.

- Class I (low to moderate risk)
- Class II (moderate to high risk)
- Class III (high risk)

How a device is classified impacts whether the device must be “FDA approved” or “FDA cleared”. However, all medical device companies must register with the FDA to sell their device in the United States.

FDA-Cleared Devices

- FDA clearance is granted to Class II medical devices that can prove substantial equivalence to a previously approved or cleared medical device, or “predicate.”
- Medical device companies can achieve FDA clearance for Class II devices through 510(k) premarket notification.
- The 510(k) premarket notification process does not require comprehensive safety and efficacy testing (e.g., human trials).
- Example: eyeglass lens technology to slow myopia

FDA Approved

- All Class III devices must receive FDA approval.
- The FDA “approves” Class III devices through a premarket approval (PMA) process.
- A PMA application is required for device manufacturers to demonstrate that their device is safe for its intended users.



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- If a device has not been through the PMA process, the device manufacturer should not refer to or market the product as “FDA approved.”
- Some Class II devices are also required to go through the PMA application process.
- Class II devices that can be proven to be substantially equivalent to an approved device or a “predicate” device can pursue FDA clearance through 510(k) premarket notification, but those without a predicate will need to follow the PMA or De Novo process. The De Novo pathway can be used for devices that do not have a predicate but can be proven to fall into Class I or Class II.
- Example: devices to treat signs and/or symptoms of dry eyes.

Consideration of FDA approval is critical when purchasing new equipment for an optometric practice. Often, doctors first will consider patient needs, price and whether additional staff training is feasible. However, understanding the regulatory requirements and environment is a must. Doctors of optometry should inquire with company representatives about their product’s status with the FDA and understand how companies offering similar equipment engage with the FDA.