

# All About Red Light Therapy

## *Claims, Compliance, and Clear Language*

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**S**alon owners win with simple, accurate language. Red light therapy is popular, yet terms like approved, cleared, registered, listed, ILY, and 510(k) often get mixed up. Use this guide to keep your ads clean, your staff aligned, and your clients well informed.

### The Regulators

**FDA role:** The U.S. Food and Drug Administration oversees medical devices along with foods, drugs, and supplements. Its authority stems from federal law adopted in 1938 to keep unsafe or misleading products off the market and to police labeling and claims.

**FTC role:** The Federal Trade Commission focuses on advertising. It requires that marketing be truthful, not misleading, and supported by reliable evidence.

**Bottom line for you:** Match your language to the device's status, and keep the same wording across every channel.

### Device Categories

**FDA approved:** Reserved mostly for drugs and some high-risk Class III devices after full safety and effectiveness review. Most salon LED products are not approved.

**FDA cleared:** A Class II device has passed the 510(k) process by showing substantial equivalence to a predicate device for a specific indication. Cleared does not equal approved.

**Registered or listed:** A manufacturer and device appear in FDA databases. This is not a review or endorsement.

**General wellness, ILY:** Very low-risk products positioned for healthy lifestyle support. Many LED tools marketed for wellness can sit here when no disease claims are made. Lasers and higher-risk devices do not fit this space.

### The Three FDA Classes

**Class I:** Lowest risk, basic controls.

**Class II:** Moderate risk, more oversight, quality systems, and usually 510(k) clearance for specific uses.

**Class III:** Highest risk, rigorous premarket review, for example implantable or life-supporting devices.

### 510(k) in Practical Terms

**What it signals:** The company showed that its device is substantially equivalent to an already marketed device for a specific indication, for example mild to moderate inflammatory acne, temporary relief of minor pain, or treatment of facial wrinkles.

**How to verify:** Ask for the 510(k) number and the official "Indications for Use." Confirm that the company name, model, and indication match the product you own or plan to buy. Keep a copy of the summary in your files.

**What it does not grant:** The right to broaden claims. Clearance is not approval, and it does not cover off-label uses.

### Scope of Practice: Legal Reality

It is illegal in the United States, Canada, and most other jurisdictions for unlicensed practitioners to diagnose, treat, cure, or prevent any medical or psychological disease, disorder, or condition, and to use language that implies those activities. Qualified professionals may provide photobiomodulation within their scope, provided they do not claim to diagnose, treat, cure, or prevent disease outside what is authorized for the device or their license.

Non-licensed providers must avoid terminology reserved for licensed clinicians, for example patient, prescribe, and treatment of disease, and must present services as wellness focused. Light therapy services delivered by non-licensed practitioners are non-medical in nature and should be oriented to comfort, recovery, appearance, and quality of life.

If you hold a professional license, consult your board and practice act. It is your responsibility to determine whether light therapy sits within your scope and what terminology is permitted, including whether you may refer to patients, treat, or prescribe.

## Words and Phrases to Handle With Care

Avoid these verbs unless your device is authorized for that exact purpose: **treat, cure, mitigate, prevent, diagnose**. Using them in ads, brochures, conversations, emails, websites, or social posts for non-authorized purposes can be considered misbranding and can create regulatory risk.

## What You Can Safely Say About PBM

Many LED photobiomodulation devices are positioned for wellness, appearance, and recovery. Some models also have 510(k) clearances for narrow indications. If you are not relying on a clearance, remain in the wellness lane.

## Generally acceptable wellness phrasing

- Red light therapy can help reduce inflammation.
- Sessions encourage healthy local circulation.
- Sessions support relaxation and general well-being as part of a balanced routine.

## Structure and function statements

- Light therapy can ease muscle stiffness.
- Photobiomodulation can reduce everyday pain sensations.
- Using light can support greater comfortable range of motion.

Keep these tied to normal structure and function, not disease treatment.

## Conditional claims that require a clearance

Only use indications such as acne treatment, temporary relief of minor pain, or treatment of facial wrinkles if your exact device holds

that indication. Mirror the approved language, frequency, treatment area, and population.

## High-risk claims to avoid

Do not imply diagnosis, treatment, cure, mitigation, or prevention of named diseases or psychological conditions without the matching authorization.

## Model Language

### Class II device example

“Our wellness spa uses light therapy to provide temporary relief of minor pain, stiffness, and muscle spasms, and to temporarily improve local blood circulation, helping clients feel and function better in everyday life.”

### ILY wellness example

“Light therapy is a health and wellness modality that supports a healthy lifestyle. Sessions can ease everyday discomfort, promote circulation, encourage cellular renewal processes, reduce stress, and enhance relaxation.”

### Client-facing description

“Light therapy devices deliver targeted wavelengths to living tissue. When absorbed, these wavelengths can promote circulation, lessen everyday aches, and support cellular renewal. We use these tools to help clients manage stiffness, minor pain, and muscle spasms, and to temporarily increase local blood flow, with the goal of improving day-to-day quality of life.”

## Marketing Workflow That Keeps You Safe

### Inventory and align

Build a one-page table for each device with model, pathway, and approved phrases. Keep it at the front desk and in your content library.

### Mirror indications when applicable

If you cite a clearance, quote the indication precisely, and follow

**“Clear words, aligned claims, confident marketing.”**

labeled parameters for area, frequency, and population.

### Use wellness language when not citing a clearance

Say supports, promotes, helps the appearance, reduces inflammation, encourages circulation, and supports relaxation.

### Keep channels consistent

Website, booking app, signage, brochures, scripts, reels, and captions should match. Train staff to stay within lanes and refer medical questions to clinicians.

### Staff Script

- Say “FDA cleared for [indication]” only if you can name the indication and the 510(k) number upon request.
- Otherwise, use wellness and structure-function language.
- Avoid the five high-risk verbs unless authorized.
- Treat every script and caption as if a regulator will read it.
- When unsure, step back to wellness phrasing or refer out.

### Final Takeaway

Lead with wellness, keep claims precise, and match your language to each device's status. Use phrases like **reduces inflammation, encourages healthy circulation, and supports relaxation** when you are not relying on a medical indication. When you do cite a clearance, mirror the exact wording. Train the team, audit your materials quarterly, and scale your marketing with confidence. •