Leveraging FDA Guidance on CFL to Demonstrate Value for Medical Devices

Using real-world data and value-driven messaging to support market access, stakeholder engagement, and regulatory alignment.

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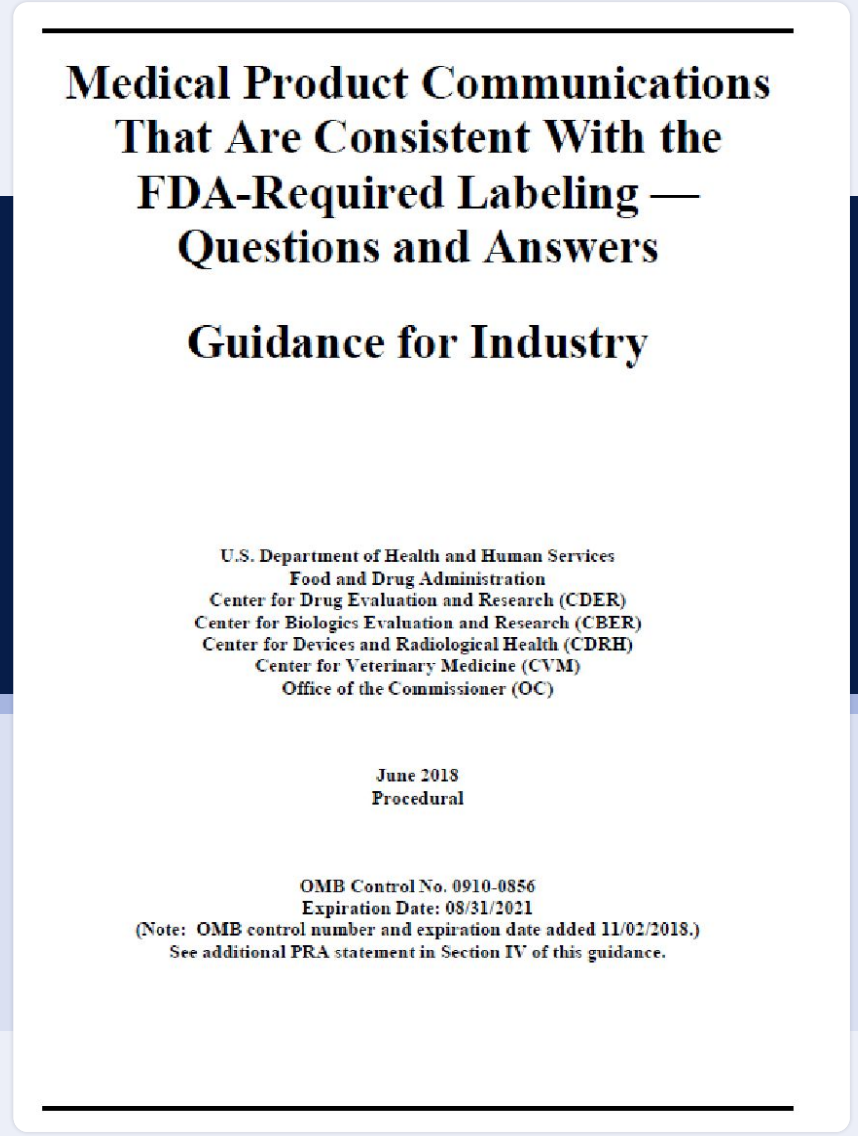

Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Veterinary Medicine (CVM)
Office of the Commissioner (OC)

June 2018
Procedural

OMB Control No. 0910-0856
Expiration Date: 08/31/2021
(Note: OMB control number and expiration date added 11/02/2018.)
See additional PRA statement in Section IV of this guidance.

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CFL is a “Must Use” Strategic Communication Tool for Any Restricted Marketed Medical Device

What is CFL?

CFL = **Consistent with FDA-Required Labeling** — a pathway for firms to **communicate helpful product information** outside the approved labeling, **without triggering a new intended use,** so long as:

- The use is still within **restricted device** scope
- The communication is **truthful, non-misleading,** and
- The content is **supported by “scientifically appropriate and statistically sound” (SASS) evidence**

Why It Matters for Value Demonstration

CFL gives firms a **regulated way** to:

- **Present RWE,** long-term effectiveness, or real-world safety
- **Differentiate the restricted device** in a competitive landscape
- Communicate **economic, clinical, or patient-experience benefits**
- Align messaging with **payer priorities and stakeholder needs**

Types of CFL-Compliant Value Communications

Type of Value-Based CFL Communication	Example (with CFL-aligned framing)
Comparative efficacy/safety (head-to-head or RWE)	In a real-world study, Device A showed X% complication rates vs. Device showed Y% B.
Patient-reported outcomes (PROs)	Patients reported X% mobility and Y% satisfaction with Device A in a post-market survey.
RWE on long-term safety or performance	Registry data over 24 months showed X% pain reduction and Y% device retention rates.
User convenience / operations	Setup time was X vs. older model's Y.
Economic impact / cost-convenience	In a health system budget impact model, use of Device A reduced reintervention costs vs. Device B. (with appropriate assumptions disclosed)
Adverse event mitigation via use optimization	Patients using Device A for shorter intervals more frequently experienced fewer side effects. These findings were observed in a registry and are exploratory.
Subgroup outcomes	Elderly patients had similar outcomes as younger patients in our pivotal trial. (No superiority implied; if not prespecified, state limitations)
Mechanism of action (if in label)	Device works by stabilizing joint alignment; clinical effect is linked to improved gait mechanics (per labeling).

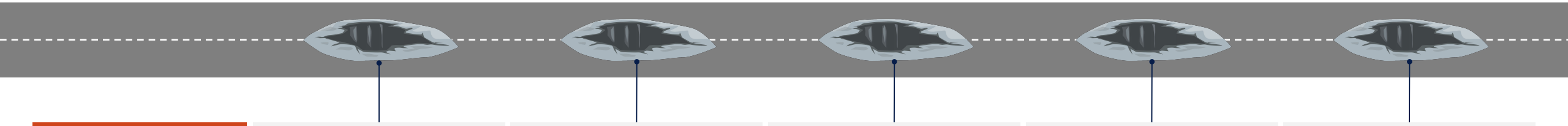
Guiding Principle for Compliant CFL Communications

Observational data -> **Descriptive** Claim

Post hoc analyses -> **Suggestive** Claim (with caution)

Pre-specified, powered, statistically valid data -> **Definitive** Claim

Common CFL Pitfalls to Avoid
Claim must not overstate the evidentiary support



Misleading Messaging	"**Better** than Competitor Y" (no design to test this)	"**Reduces** hospitalizations" (not in labeling)	"**Proven** safer for elderly"	"**Statistically significant** ($p<0.05$)" (post hoc)	"Can be used at home" (not in labeling)
Why It's a Problem	Superiority claim not supported by appropriate evidence	Suggests a new indication	Implies subgroup superiority	Suggests rigor where none exists	Off-label use environment
CFL-Compliant Alternative	"In a real-world study, Device A showed X% complication rates vs. Device showed Y% B. Study not designed to test superiority."	"In a retrospective review, X% hospital readmissions were observed. This was not a pre-specified endpoint; results are exploratory."	"Subgroup analyses suggest comparable outcomes in patients 65+. Not powered to detect subgroup differences."	"Observed numerical differences were not statistically tested or powered to detect differences."	"Device is cleared for hospital settings. Use outside labeled environments has not been evaluated."

In addition to evidentiary support, CFLs must also be consistent with labeling

Device Type	PMA Devices (Class III)	510(k)-Cleared Devices	510(k)-Exempt Devices
Pathway to CFL-Compliant Value Communication	Use the **CFL three-factor test** to assess if the communication fits within labeling	Use the **510(k) Modifications Guidance** to assess whether a communication would **trigger a new 510(k)**	Use **product classification limits** under 21 CFR 862–892

Three-Factor Test (PMA Devices Only)

Ask:

1. Is the communication about a **different use** than approved?
2. Does it introduce **greater health risk**?
3. Can the product be used **safely and effectively as directed**?

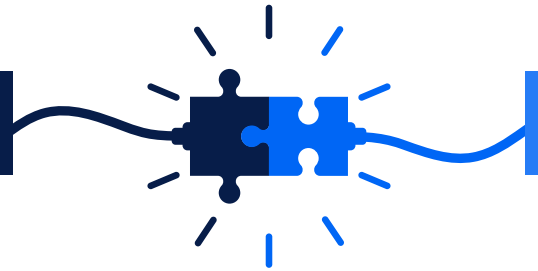
If the answer is **No to all**, the communication may be eligible for CFL.

Note: If your device is OTC, CFL Guidance does not apply

Current State:
Value + Compliance = Adoption

Use CFL to

- Share RWE, PROs, and economic data — responsibly
- Align **commercial and regulatory messaging**
- Create **evidence-informed materials** for:
  - Clinicians
  - Patients
  - Payers
  - Policymakers



Stay CFL-Compliant by

- Ensuring the **intended use hasn't changed**
- **Not overstating** findings from observational or exploratory data
- Clearly explaining **study design and limitations**
- Framing content as **contextual and supportive**, not promotional or comparative unless justified

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CFL-SASS Evidence Collaborative: Addressing the Evidence Gap in FDA Guidance

The Problem

The FDA CFL guidance (June 2018) requires promotional communications be supported by evidence that is "scientifically appropriate and statistically sound" (SASS), but does not define what constitutes SASS evidentiary support. This creates uncertainty for pharmaceutical and device companies about what evidence meets SASS standards and how to evaluate real-world evidence (RWE) for CFL.

> ***"Any data, studies, or analyses relied on should be scientifically appropriate and statistically sound..." — FDA Q.6/A.6***

The Solution

The **CFL-SASS Evidence Collaborative** is a multi-stakeholder consortium between industry, ISPOR, and the National Pharmaceutical Council (NPC). Using rigorous Delphi panel methodology with leading RWE and regulatory experts, the collaborative is developing:

- **Consensus Statements** on how RWE can meet SASS standards for CFL
- **SASS Checklist** for evaluating RWE for CFL internally at firms

Participating Organizations

Industry Sponsors (14 Companies)

Bristol Myers Squibb

Lilly

GILEAD

Johnson&Johnson

NOVARTIS

novo nordisk

Otsuka

Pfizer

sanofi

SERVIER

** AbbVie serves as Industry Co-chair*

Supporting Organizations

ISPOR
Improving healthcare decisions

National Pharmaceutical Council

Expected Outcome of Consortium is to Clarify RWE Based Evidentiary Requirements for CFL Communications

You **don't need trial evidence**, but **your evidence must match your claim**.

What's Acceptable

- Registry data with disclosed limitations
- Subgroup analyses
- Bench studies
- Administrative Claims data
- Patient-reported outcomes

What's Not

- Claims (e.g., "superiority", "non-inferiority", "statistical significance") based on anecdotal or speculative data
- Non-prespecified subgroup results presented as conclusive
- Unsupported comparative or superiority messaging
- Misleading use of statistics

"The CFL-SASS Evidence Collaborative provides consensus standards for matching RWE sources to CFL communication types—enabling confident, compliant value demonstration across the product lifecycle."