

Labeling Compliance Checklist

Ensure your promotional materials meet regulatory standards with this comprehensive checklist.

1. General Compliance Requirements

- **Accurate and Non-Misleading Content:**

- Verify all statements are truthful and supported by substantial evidence.
- Avoid exaggerated claims that could mislead the audience.

- **Consistency with Approved Labeling:**

- Ensure promotional materials align with the FDA-approved labeling or package insert.
- Avoid off-label promotion unless explicitly allowed by regulations.

- **Proper Branding and Trademark Use:**

- Use correct proprietary (brand) and established (generic) names.
 - Display the generic name in proximity to and with equal prominence as the brand name (21 CFR 201.10).
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2. Regulatory Disclaimers

- **Fair Balance:**

- Present risks with equal prominence and readability as benefits.
- Ensure balanced discussion of efficacy and safety.

- **Required Statements:**

- Include all required FDA statements, eg:
 - “This product is not intended to diagnose, treat, cure, or prevent any disease.” (for dietary supplements).
 - Indications, contraindications, warnings, and precautions for prescription products.

- **Important Safety Information (ISI):**

- Prominently display ISI on print and digital materials.
 - Use clear, legible fonts and avoid obscuring ISI with design elements.
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3. Product-Specific Requirements

- **Medical Devices:**

- Include specific indications for use.
- Avoid implying broader uses than the cleared or approved indications.

- **Drugs and Biologics:**

- Use approved language for indications and usage.
- Include dosage, administration, and risk information consistent with the prescribing information.

- **Dietary Supplements:**

- Ensure claims comply with DSHEA (Dietary Supplement Health and Education Act).
 - Use structure-function claims only with the appropriate disclaimer.
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4. Content Presentation

- **Readable Format:**

- Use easily legible font sizes and styles.
- Avoid small print, low contrast, or distracting graphics that make safety information hard to read.

- **Visual and Audio Materials:**

- Ensure spoken content matches visual content in video promotions.
- Include subtitles for disclaimers and safety information.

Digital Compliance:

- Ensure risk information is prominently displayed on websites and digital ads.
 - Avoid "hidden" safety information in hyperlinks or hard-to-access sections.
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5. Substantiation and Evidence

- **Clinical Evidence:**

- Claims must be supported by well-designed clinical studies.
- Ensure studies cited are relevant, up-to-date, and statistically significant.

- **Comparative Claims:**

- Substantiate any superiority or comparative claims with head-to-head clinical trials.
- Avoid implying equivalence or superiority without evidence.

- **Endorsements and Testimonials:**

- Ensure testimonials represent typical experiences.
 - Disclose material connections between the company and the testimonial source.
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6. Promotional Channels

- **Social Media Posts:**

- Include necessary disclaimers and risk information, even in short-form content.
- Monitor for user-generated content that could imply off-label promotion.

- **Email Campaigns:**

- Ensure compliance with labeling and risk information requirements in email text and attachments.
- Avoid misleading subject lines or headers.

- **Websites and Landing Pages:**

- Prominently display safety and risk information on all relevant pages.
 - Include easy access to the full prescribing information.
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7. Legal and Regulatory Review

- **Internal Review:**

- Conduct regular internal reviews of all promotional materials.
- Maintain documentation of review and approval processes.

- **Submission to FDA (if required):**

- Submit promotional materials to the FDA's Office of Prescription Drug Promotion (OPDP) or the Center for Devices and Radiological Health (CDRH), if applicable.
- Keep records of submissions and FDA responses.

- **Compliance with Local and Global Regulations:**

- Ensure materials meet FDA, FTC, or EMA requirements, as applicable.
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8. Recordkeeping and Audit Readiness

- **Maintain an Archive:**

- Store final versions of all promotional materials, including approvals and review notes.
- Retain records for at least 3 years (or as required by regulations).

- **Monitor for Updates:**

- Regularly update materials to reflect changes in product labeling, safety information, or regulatory requirements.
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This checklist ensures your promotional materials comply with regulatory standards, protecting your organization from legal risks and maintaining customer trust.