

Massage Oil & Muscle Rub Label Checklist

Complete before you design labels or request quotes. Numbers in brackets refer to the sources below.

Brand / product

Date

BOTH PRODUCT TYPES

- ☐ Product identity and net contents
- ☐ Claims checked against intended use (label, website, marketplace listings, ads) [4]
- ☐ U.S. address, phone number or (for cosmetics) website for adverse event reports [11][12]
- ☐ Child-resistant closure if a liquid contains more than 5% methyl salicylate [7]

COSMETIC MASSAGE OIL

- ☐ Ingredient declaration
- ☐ No pain, ache or muscle-relief wording anywhere [3]
- ☐ MoCRA product listing filed; safety substantiation on file [10]

OTC MUSCLE RUB

- ☐ Active ingredient and strength inside the M017 range [1]
- ☐ Drug Facts headings in the required order [5]
- ☐ M017 warnings and directions for your exact actives [1]
- ☐ Labeler code obtained; NDC on the label [6]
- ☐ Drug listing submitted by the manufacturer [6]

Notes

SOURCES

1. FDA, OTC Monograph M017: External Analgesic Drug Products for OTC Human Use (posted May 2, 2023)
2. FDA, Final Administrative Order OTC000033 (M017)
3. FDA, "Aromatherapy"
4. FDA, "Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)"
5. 21 CFR 201.66, OTC drug labeling format
6. 21 CFR 207.33, National Drug Code
7. 16 CFR 1700.14, substances requiring special packaging
8. CPSC, Earth Sonnets wintergreen essential oil recall (March 18, 2020)
9. Federal Register, OTC Monograph Drug Facility Fee Rates for Fiscal Year 2026 (March 18, 2026)
10. FDA, "Modernization of Cosmetics Regulation Act of 2022 (MoCRA)"
11. FDA guidance, Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application (Sept 2009)
12. ArentFox Schiff, MoCRA labeling (adverse event contact, Dec 29, 2024)
13. PMG, "Private Label vs Custom Formulation"
14. PMG, "OTC & Specialty"

General planning aid, not legal or regulatory advice. Confirm requirements with your manufacturer and regulatory reviewer.