

OTC Acne Launch Checklist

Brand / product

Prepared by

Date

CLASSIFICATION AND FORMULA

1. Claims decided: Will the label, listing or ads say "treats acne," "clears breakouts" or similar? If yes, this is an OTC drug.

Notes

2. Active chosen: benzoyl peroxide (2.5–10%), salicylic acid (0.5–2%) or sulfur (3–10%), or a permitted sulfur/resorcinol combination

Notes

3. Format chosen: cleanser, toner, pad, gel, spot treatment or leave-on lotion

Notes

LABEL AND REGISTRATION

4. Drug Facts panel drafted using M006 wording, and packaging sized to fit it

Notes

5. Labeler code obtained in your brand's name

Notes

6. Manufacturer's drug establishment registration confirmed as current

Notes

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QUALITY, MARKETING AND BUDGET

7. Stability and expiration dating plan agreed, including benzene testing for benzoyl peroxide

Notes

8. Marketing copy reviewed so website, Amazon and social claims match the monograph

Notes

9. Volume and cash planned around OTC minimums, not cosmetic ones

Notes

PROJECT SNAPSHOT

Active ingredient and %

Format

Target first-run units

Target launch date

Path (stock OTC formula or custom formulation)

PMG OTC starting points

Stock OTC formula: typically 5,000 units, 90–150 day launch window

Custom OTC formulation: typically 10,000+ units, 6–12 months

Cosmetic private label (no acne claims): from 1,000 units, 60–90 days

Planning an acne line?

Request a consultation and tell us your claims, format and target volume.

productmgmtgroup.com/contact

For planning only; not legal or regulatory advice. Confirm requirements against FDA sources before launch.