SCE 0612 Public Evidence Appendix

Exosome marketing claims

Literature review date: September 9, 2026

Controlling principle. Marketing language must not substitute for product identity, manufacturing quality, mechanistic evidence, human clinical evidence, safety data, or jurisdiction-specific regulatory status.

Claim-evaluation map

Marketing issue	What the claim may imply	What evidence is actually needed
Particle counts without purity data	Large particle numbers can imply a precisely characterized or potent product.	Identity, purity, contaminant assessment, characterization, potency, dose-response, safety, and use-specific evidence.
Undefined source cells	Terms such as 'stem-cell exosomes' can imply a defined biological source.	Producer-cell type, tissue origin, donor/cell qualification, culture history, cell health, and manufacturing process.
Unvalidated potency	Particle number, cargo detection, or appearance can be presented as evidence of activity.	A relevant, reproducible potency assay linked to the intended biological mechanism and product amount.
Stem-cell-free safety claims	Absence of living cells can be framed as absence of meaningful risk.	Product-specific contaminant, sterility, immunologic, biological-activity, dose, route, and human safety evidence.
Cosmetic versus therapeutic claims	Cosmetic language may coexist with claims that imply treatment or alteration of disease or body function.	Interpret the actual intended use and claim, then assess the evidence and jurisdiction-specific regulatory framework separately.
Research-use-only products used clinically	A research label can obscure a mismatch between product design/testing and clinical administration.	Clinical-grade manufacturing, identity, purity, sterility, potency, safety, traceability, and applicable regulatory status.

Key evidence conclusions

Quantitative language is not automatically meaningful evidence. Billions or trillions of detected particles do not establish exosome identity, purity, potency, safety, or effectiveness.

Source matters. EV composition depends on producer-cell identity, tissue source, culture conditions, cell state, and manufacturing; evidence should not be transferred across undefined or non-equivalent products.

Safety and efficacy remain product- and use-specific. 'Cell-free' or 'stem-cell-free' does not eliminate risks from biologically active cargo, contaminants, route, dose, sterility failures, or unintended effects.

Regulatory status and evidence are separate questions. A product's legal or regulatory classification in a jurisdiction does not by itself prove or disprove biological effectiveness; both should be described accurately and separately.

Principal references

1. Théry C, Witwer KW, Aikawa E, et al. Minimal information for studies of extracellular vesicles 2018 (MISEV2018). J Extracell Vesicles. 2018;7:1535750.

2. Welsh JA, Goberdhan DCI, O'Driscoll L, et al. Minimal information for studies of extracellular vesicles (MISEV2023): From basic to advanced approaches. J Extracell Vesicles. 2024;13:e12404.

3. Witwer KW, Van Balkom BWM, Bruno S, et al. Defining mesenchymal stromal cell (MSC)-derived small extracellular vesicles for therapeutic applications. J Extracell Vesicles. 2019;8:1609206.

4. U.S. Food and Drug Administration. Public safety notifications and consumer information concerning unapproved regenerative medicine products, including exosome products.

5. Applicable jurisdiction-specific frameworks for cosmetics, drugs, biologics, human research products, advertising, labeling, and clinical investigation.