DSHEA 10.0

Technical Appendix
Detailed Framework, Definitions, and Safeguards

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Purpose of This Appendix

Provides technical detail referenced during the session

Designed for policymakers, regulators, and industry experts

Not a substitute for statutory text, but a roadmap to it

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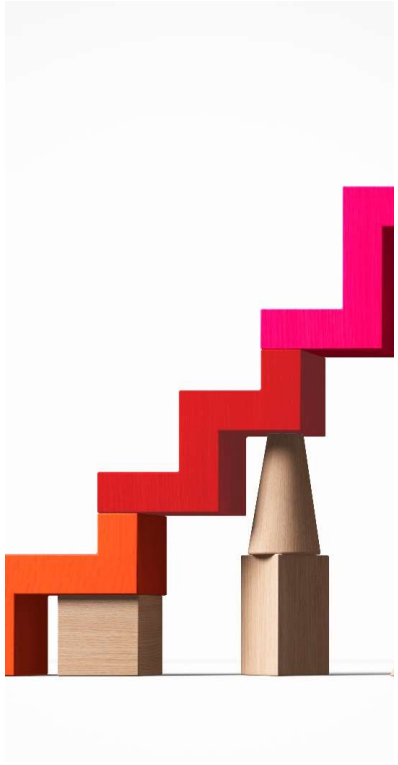
DSHEA 10.0: Architectural Overview



- Post-market regulatory framework remains intact
- Visibility, not permission, is the organizing principle
- Clear statutory rules replace guidance-driven discretion
- Authority is clarified and bounded for all parties

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Mandatory Post-Market Product Listing

Listing required after market entry, not before

Failure to list renders product adulterated as a matter of law

Required information limited to label-level data

No premarket approval, clearance, or conditioning

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Statutory Guardrails on Listing Authority

- FDA may not delay or deny marketing based on listing content
- Prohibition on demands for proprietary formulations
- Good-faith cure for errors and clerical safe harbor
- Use of listing data limited to post-market oversight

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User Fee Structure

- Dedicated congressional authorization
- Prohibited from supporting premarket approval
- Funds limited to post-market oversight activities
- Measurable performance goals
- Annual reporting

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Modernizing Dietary Ingredient Definitions

Bioidentical synthetic and semi-synthetic ingredients included

Chemical and molecular identity is threshold criterion

Inclusion paired with mandatory FDA notification

No automatic grandfathering for new bioidenticals

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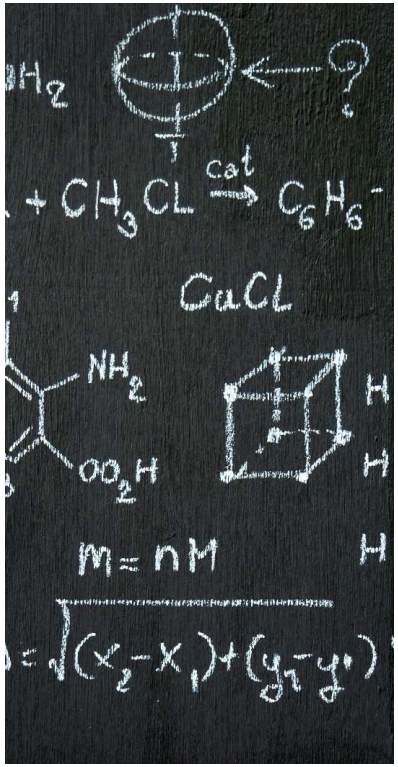
Safety Equivalency Review



- 90-day subchronic oral toxicity study or equivalent data
- Bioavailability and pharmacokinetics where appropriate
- Focus on exposure, metabolism, and toxicological profile
- Validate methods and GLP or equivalent standards

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Manufacturing-Related Safety Considerations

Evaluation of impurities, residual solvents, and contaminants

Alignment with existing CGMP requirements

Fermentation products reviewed for non-target substances

Origin-neutral application to natural and synthetic ingredients

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What Does Not Trigger NDI Status?

- Manufacturing process or scale changes alone
- Dose or serving size changes alone
- Absent demonstrable impact on safety profile
- FDA must show specific safety rationale

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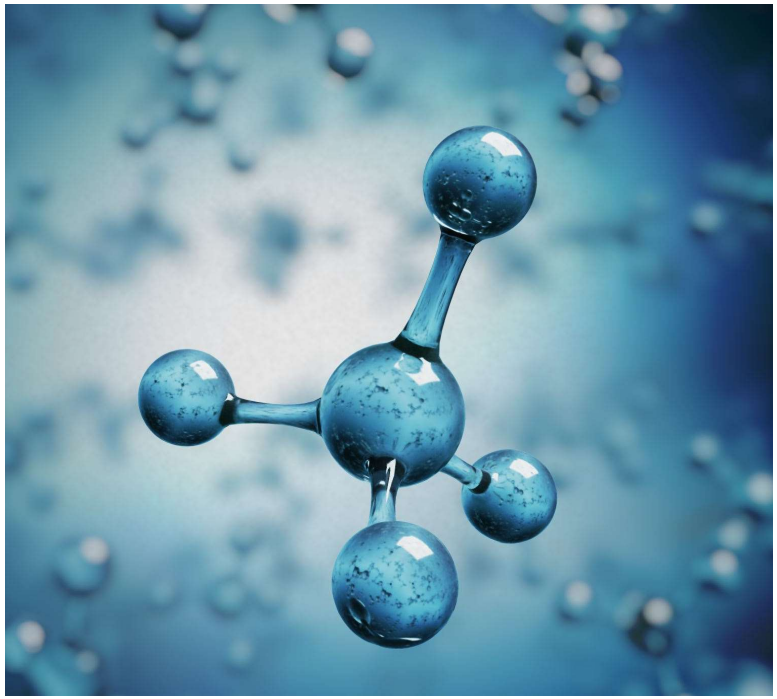
Clarifying Drug Preclusion

- Preclusion limited to identical conditions of use
- Dose, route, population, and exposure are determinative
- Prior lawful supplement marketing preserved
- Science-based differentiation replaces categorical exclusion



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Cosmetic vs. Drug Boundary

- Local structure/function claims permit for cosmetics
- Systemic or transdermal delivery claims = drug
- Boundary grounded in toxicology and exposure
- No impact on dietary supplement status or ingestion

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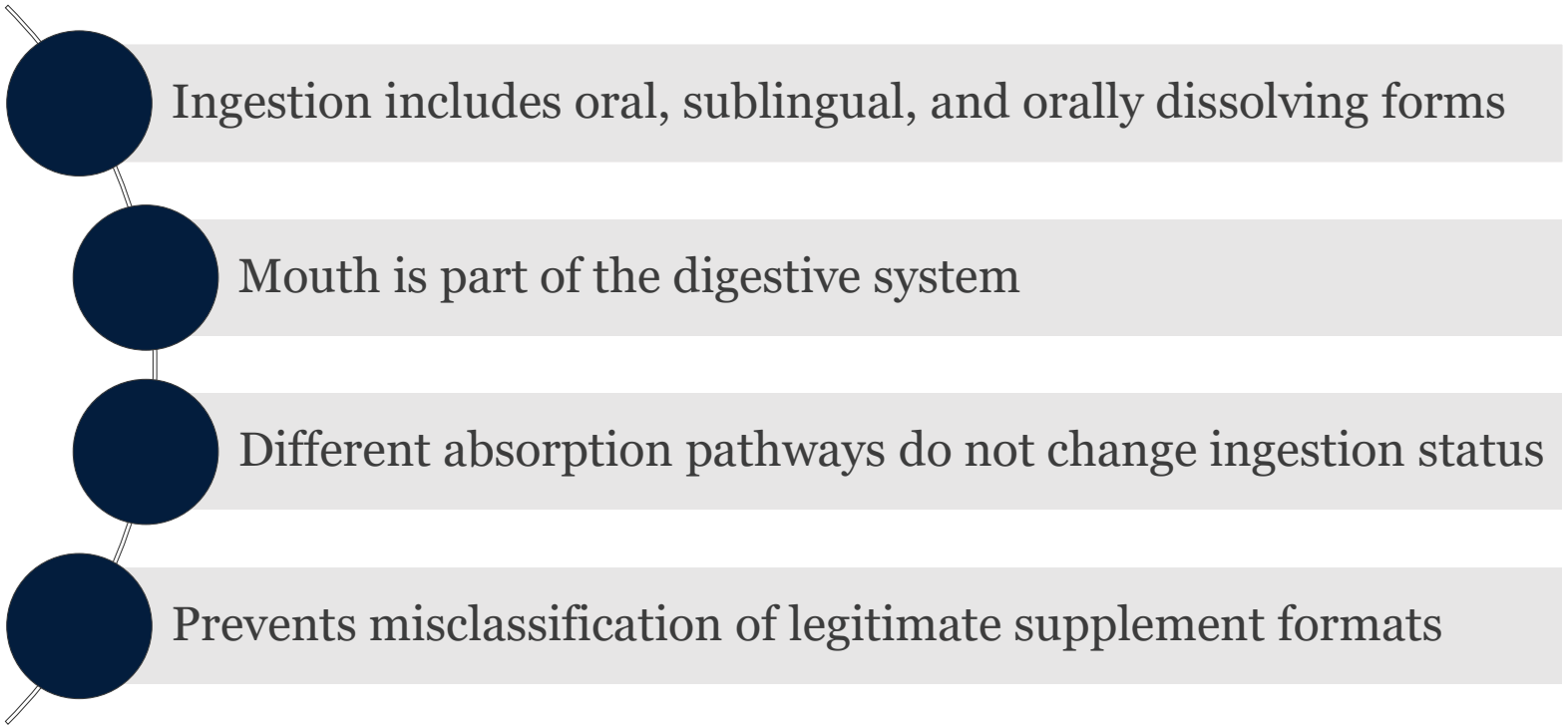
Clarifying Ingestion



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Enforcement and Market Reality

- Global digital commerce limits perfect control
- Existing import restrictions remain in effect
- Clarity enables targeted, risk-based enforcement
- Framework designed for realistic enforcement capacity

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Why DSHEA 10.0 Is Durable

Harder to manipulate by regulators or bad actors

Reduces reliance on guidance and discretion

Aligns incentives toward compliance and transparency

Built for continued market evolution

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Using This Framework

Supports informed policy discussion post-session

Intended to complement, not replace, statutory text

Provides common reference point for stakeholders

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