RegenMed

ARTICLE

THE END OF SELF-CERTIFICATION

www.rgnmed.com | circles@rgnmed.com

THE REGULATORY CATALYST: RECLAIMING OVERSIGHT OF THE FOOD SYSTEM

In early 2026, the FDA moved to close a decades-old regulatory gap known as the **"Generally Recognized as Safe" (GRAS)** loophole. For years, this provision allowed food and supplement manufacturers to bypass formal FDA approval by self-declaring that their chemical additives were safe, often based on internal or proprietary research that was never shared with the public or the agency.

Under the current administration, the FDA has fundamentally reversed this "honor system." Commissioner Marty Makary has initiated a comprehensive review of chemical additives, starting with the removal of nine artificial petroleum-based dyes from the U.S. food supply. More importantly, the agency now requires that any substance seeking GRAS status must be backed by transparent, peer-reviewed, and — most critically — real-world performance data. This shift aligns with the new **"RealFood.gov"** initiative, which prioritizes protein-dense, minimally processed nutrition over the refined carbohydrates that have dominated the American diet for fifty years.

THE EVIDENCE GAP: SELF-REPORTING VS. OUTCOME ENGINEERING

This regulatory pivot has created an immediate "Evidence Gap" for the food, beverage, and nutraceutical industries. For years, these sectors relied on short-term, "Administrative Proxies" to justify safety. These proxies — often limited to acute toxicity studies in animals — lack the clinical depth required to prove long-term metabolic safety in humans.

As the FDA and the newly formed **Administration for a Healthy America (AHA)** begin to investigate the "root causes" of the chronic disease epidemic, the industry can no longer hide behind self-certified safety claims. To remain on the market, manufacturers must now provide **Verified Clinical Veracity** regarding how their products impact human inflammatory markers, insulin sensitivity, and the gut microbiome over time.

THE CIRCLE SOLUTION: THE INFRASTRUCTURE OF NUTRITIONAL TRUTH

The **Circles** platform provides the necessary **Regulatory-Grade Governance** to bridge this gap. By utilizing **Observational Protocols (OPs)**, Circle enables manufacturers, researchers, and clinicians to track the real-world metabolic impact of nutritional interventions with the same rigor as a pharmaceutical trial.

Audit-Ready "Ground Truth": Circles capture **Standardized Longitudinal Scores** — including blood glucose levels, inflammatory cytokines, and body composition — directly at the point of care. This provides a permanent, timestamped audit trail that satisfies the FDA's new demand for transparent safety data.

Outcome Engineering: By moving beyond "Data Exhaust," Circles allow for the creation of high-veracity datasets that prove the efficacy of "food as medicine." This is critical for companies looking to align with the AHA's focus on reversing chronic disease.

Insurable Integrity: For food and supplement brands, providing data through a Circle creates a "shield" of **Insurable Integrity**. It demonstrates a commitment to transparency that minimizes the risk of federal enforcement actions or consumer litigation.

STRATEGIC OUTCOME: VALUATION VIA COMPLIANCE-AS-AN-ASSET

In the legacy regulatory environment, safety data was a compliance cost. In the 2026 environment, it is a valuation driver. Companies that continue to rely on the "GRAS" loophole will be viewed as high-risk liabilities.

In contrast, organizations that utilize Circles to provide **Verified Clinical Veracity** are reclassified as **Tech-Enabled Assets**. By owning the **"Ground Truth"** of their products' safety and efficacy, these entities can achieve **Multiple Expansion to 12–15x**, as their data becomes a critical component of the national metabolic health infrastructure.

GET INVOLVED OR LEARN MORE — CONTACT US TODAY!

If you are interested in contributing to this important initiative or learning more about how you can be involved, please contact us*:

RegenMed | www.rgnmed.com

circles@rgnmed.com

SCAN ME

*If the links do not work for you, please download the PDF.