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MEMORANDUM

**To: Hon. Brooke Rollins, Secretary of Agriculture
Hon. Martin Makary, MD, MPH, Commissioner, Food and Drug
Administration**

**From: Andrew Langer, Director, Center for Regulatory Freedom, CPAC
Foundation**

Date: April 27, 2026

**Re: Comments on the US Food and Drug Administration’s Information
Collection Request, “Current Good Manufacturing Practice in
Manufacturing, Packaging, Labeling, or Holding Operations for Dietary
Supplements,” Docket #FDA-2026-N-0686, Fed. Reg. 2026-03589, Published
February 24, 2026**

Below are comments of the American Conservative Union Foundation's (d/b/a. Conservative Political Action Coalition Foundation) (hereinafter “CPAC Foundation”) Center for Regulatory Freedom (hereinafter “CRF”), in response to US Food and Drug Administration’s Information Collection Request, “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” Docket #FDA-2026-N-0686, Fed. Reg. 2026-03589, published February 24, 2026.

CRF is a project of the CPAC Foundation, a non-profit, non-partisan 501(c)(3) research and education foundation. Our mission is to inject a common-sense perspective into the regulatory process, to ensure that the risks and costs of regulations are fully based on sound scientific and economic evidence, and to ensure that the voices, interests, and freedoms of Americans, and especially of small businesses, are fully represented in the regulatory process and debates. Finally, we work to ensure that regulatory proposals address real problems, that the proposals serve to ameliorate those problems, and, perhaps most importantly, that those proposals do not, in fact, make public policy problems worse.

I. INTRODUCTION

The Food and Drug Administration's request for comment under the Paperwork Reduction Act presents an important opportunity to evaluate the role of information collection within the Agency's broader statutory mission. In the context of dietary supplements, where Congress has established a distinct regulatory framework, the structure and scope of recordkeeping requirements are not merely administrative matters, but foundational components of the oversight regime. As such, the evaluation of these requirements should be undertaken with careful attention to both their necessity and their practical utility.

Unlike pharmaceuticals, which are subject to premarket approval for safety and efficacy, dietary supplements operate under a post-market enforcement model. This framework places primary responsibility on manufacturers to ensure product quality and compliance, with the FDA exercising oversight through inspection, enforcement actions, and the evaluation of adverse events. In this context, the Agency does not serve as a gatekeeper prior to market entry, but rather as an enforcer of statutory standards after products are already in commerce.

Given this structure, recordkeeping and documentation requirements assume a central role. They provide the mechanism through which FDA can verify that manufacturers are adhering to current good manufacturing practices, ensure that products are not adulterated, and establish whether labeling accurately reflects product composition. These records serve not only as internal compliance tools for manufacturers, but also as the evidentiary foundation upon which FDA enforcement actions depend.

Accordingly, the central question presented by this PRA review is not whether such documentation is necessary, but whether it is appropriately calibrated to achieve its intended purpose. Recordkeeping requirements must be sufficiently robust to support effective oversight, while also being structured in a manner that avoids unnecessary burden and focuses on information that has demonstrable enforcement and public health value.

II. EXECUTIVE SUMMARY

The FDA's evaluation of information collection requirements for dietary supplement CGMP regulations should be guided by the principle that documentation is essential to the effective functioning of a post-market regulatory system, but must be disciplined and targeted to ensure practical utility.

Our comments address the following:

- **Recordkeeping requirements are indispensable to FDA's ability to detect and prevent adulteration in a framework that does not rely on premarket approval.**
- **The current burden estimates may not fully capture the variability in compliance costs across firms of different sizes and operational complexity.**
- **Certain documentation requirements risk generating diminishing marginal returns, contributing to compliance volume without corresponding increases in safety or oversight effectiveness.**

- **A more risk-based and performance-oriented approach to recordkeeping would better align regulatory burden with actual public health objectives.**
- **Opportunities exist to enhance both the quality and utility of collected information through greater flexibility and the incorporation of modern data systems.**

In applying PRA standards, the Agency should focus on ensuring that information collection requirements are not only necessary in principle, but also structured to maximize their real-world effectiveness in supporting compliance, enforcement, and consumer protection.

III. NECESSITY OF INFORMATION COLLECTION

In the absence of premarket approval requirements, FDA's ability to ensure the integrity of dietary supplements depends heavily on its capacity to evaluate manufacturing practices after products enter the market. Recordkeeping requirements provide the primary means by which the Agency can assess whether manufacturers are maintaining appropriate controls over identity, purity, strength, and composition. Without such documentation, meaningful oversight would be significantly impaired.

These records enable traceability across the production lifecycle, allowing FDA to identify the source of potential contamination, substitution, or process failures. They also support the evaluation of whether manufacturers have implemented adequate controls and whether deviations from those controls are appropriately identified and corrected. In this sense, recordkeeping is not ancillary to compliance; it is integral to the verification of compliance.

Moreover, the absence of reliable documentation would undermine FDA's ability to take timely and effective enforcement action. In a post-market system, where the Agency must often act based on observed deficiencies rather than pre-approved standards, the existence of a clear and accessible evidentiary record is essential. Without it, enforcement becomes reactive, fragmented, and less effective in preventing harm.

IV. EVALUATION OF BURDEN ESTIMATES

While the necessity of recordkeeping is clear, the burden associated with these requirements warrants careful scrutiny. The estimated burden presented by FDA reflects an aggregate view of compliance activities, but may not fully account for the significant variation in operational scale, product complexity, and internal infrastructure across regulated entities.

Smaller firms, in particular, may face disproportionately higher compliance costs due to limited administrative capacity and reduced ability to absorb fixed documentation requirements. Conversely, larger firms may benefit from economies of scale and more advanced systems, enabling them to manage similar requirements with comparatively lower marginal cost. A uniform burden estimate risks obscuring these differences and may lead to an incomplete understanding of the real-world impact.

Additionally, certain recordkeeping requirements may involve overlapping or duplicative documentation, increasing the volume of records without necessarily improving their informational value. To the extent that such duplication exists, it should be carefully examined to

determine whether it contributes meaningfully to oversight or simply adds to administrative complexity.

V. UTILITY AND PRACTICAL VALUE

The effectiveness of any information collection regime depends not only on the quantity of data collected, but on its quality and usability. High-value records—such as those related to identity testing, batch production, and quality control—play a direct role in ensuring product integrity and supporting enforcement actions. These should remain central components of the CGMP framework.

At the same time, there is a risk that excessive or poorly targeted documentation requirements may lead to a “check-the-box” compliance environment. In such cases, firms may focus on generating records to satisfy formal requirements rather than on ensuring that those records reflect meaningful control over manufacturing processes. This can dilute the effectiveness of the system by prioritizing form over substance.

A more disciplined approach would distinguish between records that are essential for demonstrating compliance and those that provide limited incremental value. By focusing on the former, FDA can enhance both the clarity and the utility of the information it collects, while reducing unnecessary burden on regulated entities.

VI. RECOMMENDATIONS FOR REFINEMENT

To better align information collection requirements with PRA principles, FDA should consider adopting a more risk-based approach to recordkeeping. This could involve tailoring requirements based on factors such as product risk profile, manufacturing complexity, and firm size, thereby ensuring that regulatory obligations are proportionate to the potential for harm.

The Agency should also explore opportunities to increase flexibility in how records are maintained and reported. Allowing for greater use of digital systems and automated data collection could improve accuracy, reduce redundancy, and enhance the accessibility of information during inspections and enforcement actions.

Importantly, any effort to reduce burden should preserve those elements of documentation that are essential to verifying compliance and preventing adulteration. The objective should not be to eliminate recordkeeping, but to refine it in a manner that maximizes its effectiveness while minimizing unnecessary administrative cost.

VII. CONCLUSION

The FDA’s review of information collection requirements under the Paperwork Reduction Act reflects an important commitment to ensuring that regulatory obligations remain both necessary and appropriately tailored. In the context of dietary supplements, where the Agency relies on post-market oversight, the role of recordkeeping is particularly significant and warrants careful consideration.

Documentation requirements under CGMP regulations are indispensable to the functioning of this framework. They provide the foundation for verifying compliance, detecting adulteration, and supporting enforcement actions. Without them, FDA's ability to carry out its statutory responsibilities would be materially diminished.

At the same time, the effectiveness of these requirements depends on their design. Overly burdensome or poorly targeted documentation can reduce efficiency, create compliance challenges, and shift focus away from substantive quality control. Conversely, insufficient documentation can weaken oversight and increase the risk of unsafe or misbranded products entering the market.

The task, therefore, is one of calibration. Information collection requirements must be structured to ensure that they capture the data necessary for effective enforcement, while avoiding unnecessary complexity and redundancy. This requires a disciplined approach that prioritizes practical utility, clarity, and proportionality.

Ultimately, the effectiveness of FDA's CGMP framework for dietary supplements will not be determined by the sheer volume of records maintained, but by whether those records provide meaningful insight into manufacturing practices and support the Agency's ability to protect public health. A well-calibrated system—one that is clear, targeted, and operationally feasible—will best serve both regulators and regulated entities, while advancing the core objectives of the statute.

Sincerely,

A handwritten signature in black ink that reads "Andrew M. Langer". The signature is written in a cursive, flowing style.

Andrew M. Langer
Director
CPAC Foundation Center for Regulatory Freedom