



**515 KING STREET, ALEXANDRIA VA 22314**

**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: February 9, 2026**

**Re: Comments on the US Food and Drug Administration’s Agency Information  
Request, “Proposed Collection; Comment Request; Establishment,  
Maintenance, and Availability of Records; Additional Traceability Records  
for Certain Foods,” Docket #FDA-2025-N-4250, Fed. Reg. 2025-22277,  
Published December 9, 2025**

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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 Agency Information Request, “Proposed Collection; Comment Request; Establishment, Maintenance, and Availability of Records; Additional Traceability Records for Certain Foods,” Docket #FDA-2025-N-4250, Fed. Reg. 2025-22277, published December 9, 2025.

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.

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## Introduction

The Center for Regulatory Freedom (“CRF”) submits these comments in response to the Food and Drug Administration’s proposed extension of information collection requirements relating to food traceability recordkeeping. CRF has a long-standing record of engagement on matters involving the Paperwork Reduction Act, administrative burden, and the real-world affordability impacts of federal regulatory programs. That work has consistently focused on ensuring that information collections are disciplined, necessary, and justified by demonstrable practical utility, rather than treated as routine or self-validating exercises.

CRF recognizes and supports FDA’s core mission of protecting public health and acknowledges that rapid and effective traceback of foodborne illness outbreaks is a legitimate and important regulatory objective. Effective traceability can play a role in identifying sources of contamination, limiting the scope of recalls, and facilitating agency response during public health events. Nothing in these comments should be read as questioning the importance of food safety or FDA’s responsibility to address genuine risks in the food supply.

At the same time, this comment is intentionally narrow. CRF does not challenge the Food Safety Modernization Act itself, nor does it dispute FDA’s general authority to require certain records in support of its enforcement responsibilities. Rather, CRF’s concern is with the *scale, structure, and proportionality* of the information collection FDA now seeks to normalize through repeated PRA renewals. The question before OMB is not whether traceability is desirable in the abstract, but whether this particular collection, at this magnitude, satisfies the PRA’s statutory standards.

The Paperwork Reduction Act exists precisely to prevent paperwork from becoming a substitute for policy clarity, risk-based targeting, and statutory discipline. Congress designed the PRA to function as a meaningful gatekeeping mechanism—requiring agencies to demonstrate that each collection of information has practical utility, is no more burdensome than necessary, and does not impose costs disproportionate to its benefits. When information collection becomes expansive by default rather than justified by analysis, the PRA’s purpose is undermined.

Here, FDA seeks approval for an information collection that translates into a billion-dollar annual paperwork burden, driven by tens of millions of labor hours across hundreds of thousands of regulated entities. Yet FDA has not demonstrated that the marginal utility of this level of documentation is proportional to that burden. Assertions that records may assist in traceback, without evidence showing which records matter, how much documentation is necessary, or where diminishing returns occur, are insufficient under the PRA’s standard.

CRF’s central concern is that traceability as a *concept* is being treated as synonymous with unlimited documentation in practice. Existing commercial records already perform much of the traceback function FDA describes, and FDA has not shown why additional, uniform, and highly granular recordkeeping requirements are necessary across the entire supply chain. Without such a showing, the information collection risks becoming an exercise in administrative accumulation rather than a targeted public health tool.

Finally, these concerns cannot be separated from broader affordability and competition impacts. Large, vertically integrated firms are often able to absorb extensive paperwork requirements as overhead, while smaller and independent operators face disproportionate per-unit compliance costs. Over time, this dynamic can distort markets, accelerate consolidation, and embed

regulatory costs into the price of food without commensurate public health gains. It is within this broader economic and competitive context that CRF urges careful scrutiny of the proposed information collection under the PRA.

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## Executive Summary

The Center for Regulatory Freedom (“CRF”) submits these comments to address whether the Food and Drug Administration’s proposed extension of food traceability recordkeeping requirements satisfies the Paperwork Reduction Act’s statutory standards. CRF supports effective food safety policy and recognizes the value of timely traceback during foodborne illness outbreaks. The purpose of this comment, however, is to evaluate whether the *scale, structure, and scope* of the information collection FDA seeks to renew have been justified by demonstrated practical utility proportional to the substantial burdens imposed.

- The Paperwork Reduction Act requires agencies to demonstrate that each information collection has practical utility and is no more burdensome than necessary; generalized assertions that information may be useful are insufficient to satisfy this standard.
- FDA has not demonstrated the marginal utility of collecting billions of traceability records annually, nor has it shown which specific data elements materially improve outbreak response outcomes.
- The proposed information collection affects hundreds of thousands of entities across the food supply chain and imposes tens of millions of hours of annual paperwork burden, translating into more than a billion dollars in direct compliance costs.
- FDA’s claimed benefits—faster traceback, narrower recalls, improved compliance, and enhanced crisis management—are largely aspirational and have not been validated through retrospective or outcome-based analysis tied to the volume of records collected.
- Anecdotal examples where records assisted outbreak investigations do not establish that the current scope of documentation is necessary or that additional recordkeeping beyond existing commercial records delivers proportional public health benefits.
- Uniform, transaction-based recordkeeping requirements disproportionately burden smaller and independent operators, while larger firms are better positioned to absorb compliance costs as overhead, creating competitive distortions and accelerating market consolidation.
- Extensive paperwork requirements function as a substitute for risk-based targeting and enforcement, embedding administrative complexity into routine commerce rather than focusing regulatory attention on the highest-risk activities.
- FDA has not adequately considered lower-burden alternatives, including tiered requirements, reliance on existing commercial records, or targeted traceability measures focused on demonstrably high-risk actors and activities.

In light of these concerns, CRF urges the Office of Management and Budget to exercise its gatekeeping role under the Paperwork Reduction Act by requiring FDA to more clearly demonstrate the necessity, proportionality, and practical utility of the proposed information collection. Without such a showing, repeated renewal of this paperwork regime risks entrenching administrative burden without delivering commensurate public health benefits, undermining both affordability and the integrity of the PRA review process.

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## I. The PRA Requires Demonstrable Practical Utility, Not Aspirational Justification

The Paperwork Reduction Act establishes a clear and substantive standard for federal information collections. Agencies must demonstrate that each collection is **necessary for the proper performance of agency functions** and that the information has **practical utility**—that is, it must be expected to yield information that is actually useful to the agency in carrying out its statutory responsibilities. The PRA does not permit agencies to rely on broad programmatic objectives or generalized assertions of usefulness; it requires a showing that the specific information being collected is needed and justified.

That standard is materially different from a claim that information *could* be useful in theory. Many forms of data collection may be conceptually helpful, but the PRA demands more than theoretical plausibility. It requires **demonstrated utility**, grounded in evidence, experience, or analysis showing that the particular data elements collected meaningfully improve agency decision-making or outcomes. Absent such a showing, an information collection cannot be deemed “necessary” within the meaning of the statute.

In this proceeding, FDA’s justification for renewing the traceability recordkeeping requirements relies largely on generalized claims that additional records will facilitate faster traceback during foodborne illness investigations. While expedited traceback is a legitimate objective, FDA does not identify which specific data elements drive those improvements, how frequently they are used, or whether comparable outcomes could be achieved with narrower or more targeted information collections. Assertions that “more information” may improve response capability do not satisfy the PRA’s requirement to justify *this* information collection.

Critically, PRA review is intended to focus on **marginal benefit**, not the overall desirability of an underlying regulatory program. The relevant question is not whether traceability, as a policy concept, advances food safety goals, but whether the incremental paperwork burden imposed by this ICR produces incremental benefits commensurate with its cost. Acceptance of broad programmatic goals in lieu of marginal-utility analysis would collapse PRA review into a pro forma exercise, contrary to congressional intent.

FDA’s supporting materials do not include retrospective analysis identifying which records have materially improved outbreak investigations, reduced illness counts, or narrowed recalls, nor do they evaluate whether additional layers of documentation beyond existing commercial records have produced measurable gains. Without such analysis, it is impossible to assess whether the scale of the proposed collection reflects necessity or merely administrative preference. The absence of outcome-based validation is particularly consequential given the extraordinary volume of records encompassed by this ICR.

When agencies are permitted to renew large-scale information collections without demonstrating marginal utility, the PRA ceases to function as a meaningful constraint. Instead of serving as a disciplinary mechanism that forces agencies to justify paperwork burdens with evidence, PRA review risks becoming a procedural checkpoint that ratifies administrative accumulation. That outcome is inconsistent with the statute’s purpose and undermines OMB’s gatekeeping role.

For these reasons, FDA has not met its burden under the PRA as applied to the scope and scale of this information collection. While the agency may articulate legitimate objectives, it has not demonstrated that the specific records required—and the magnitude at which they are

collected—are necessary or possess practical utility proportional to the substantial burdens imposed. OMB should therefore require a more rigorous showing before approving renewal of this ICR.

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## II. Scope and Scale: An Economy-Wide Paperwork Regime

The information collection FDA seeks to renew applies across the full breadth of the modern food supply chain. Covered entities include manufacturers, processors, packers, holders, shippers, receivers, transporters, and importers of food operating in both interstate and intrastate commerce. In practical terms, this means that routine commercial activity—from harvesting and initial packing through distribution and final delivery—triggers recordkeeping obligations regardless of an entity’s size, risk profile, or role in any particular food safety incident.

By FDA’s own estimates, this information collection touches **hundreds of thousands of regulated entities** and governs **billions of individual transactions each year**. The scope is not limited to discrete, episodic reporting events, but rather embeds documentation requirements into ordinary, high-frequency business operations. As a result, the paperwork burden associated with this ICR is systemic and continuous, rather than occasional or event-driven.

The scale of the shipper and receiver component alone illustrates the magnitude of the regime. FDA estimates that shipping and receiving activities generate **approximately 2.9 billion records annually**, consuming **roughly 17.8 million labor hours per year**. These records are created not in response to outbreaks or investigations, but as a standing condition of routine commerce, multiplying burden as transaction volume increases.

When translated into direct compliance costs using OMB-recognized hourly labor rates, this single component of the ICR exceeds **\$1.2 billion annually**. This figure reflects only the labor cost of producing the records and does not capture additional overhead, management time, training, or systems integration expenses. Nor does it reflect opportunity costs associated with diverting labor and capital away from productive activity.

Scale matters under the Paperwork Reduction Act because paperwork burdens do not operate in isolation. When imposed across large segments of the economy, they **compound systemically**, shaping business models, supply chain design, and market participation. The PRA is explicitly concerned with preventing unnecessary accumulation of such burdens, particularly where agencies have not demonstrated that each incremental layer of documentation yields commensurate benefits.

Notably, FDA’s requirements scale primarily by **transaction volume**, not by risk, hazard profile, or market power. Entities that move large numbers of low-risk products face exponentially greater paperwork obligations than those engaged in fewer transactions, regardless of whether those transactions present heightened food safety concerns. This structure amplifies burden on high-throughput actors—including many smaller distributors and independent operators—without regard to whether the additional records materially advance traceback objectives.

In light of this breadth, FDA bears a heightened obligation under the PRA to explain why an economy-wide documentation regime of this magnitude is necessary. Yet the agency has not justified why traceback goals require coverage of this scope, nor why narrower, risk-based, or

tiered alternatives would be insufficient. Absent such justification, the scale of the proposed information collection stands as an end in itself, rather than as a means demonstrably tailored to the agency's stated objectives.

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### **III. Claimed Benefits of Traceability Recordkeeping**

In support of the proposed information collection, FDA advances a consistent set of claimed benefits associated with expanded traceability recordkeeping. These include the ability to conduct faster traceback during foodborne illness investigations, the potential to narrow the scope of recalls, the deterrent effect of documentation on unsafe practices, and improved crisis management and public confidence during food safety events. Taken together, these claims are offered to justify the breadth and persistence of the recordkeeping requirements at issue.

CRF does not dispute that records can assist traceback efforts in some circumstances. Access to shipping, receiving, and lot-level information can help reconstruct supply chains after illnesses have been identified and may facilitate agency investigations. To that extent, the concept of traceability is not inherently in conflict with food safety objectives, and recordkeeping can play a role in supporting FDA's enforcement responsibilities.

At the same time, it is important to clarify what FDA does *not* claim. The agency does not contend that the recordkeeping requirements prevent contamination from occurring in the first place, nor does it assert that they reduce the overall incidence of foodborne illness. Instead, the asserted benefits are almost entirely post hoc—focused on response and reconstruction after an outbreak has already occurred.

This distinction matters under the PRA because the primary beneficiaries of these claimed improvements are the agency itself, rather than consumers directly. Faster traceback, narrower recalls, and enhanced crisis management primarily improve FDA's internal response capacity and administrative effectiveness. While those outcomes may have secondary benefits for the public, they are not synonymous with demonstrable consumer welfare gains and must still be weighed against the substantial burdens imposed by the information collection.

Moreover, FDA has not provided quantified estimates of the benefits associated with this recordkeeping, nor has it tied those benefits to the volume or granularity of records collected. The agency does not identify how much faster traceback becomes as documentation increases, where diminishing returns occur, or whether similar outcomes could be achieved with fewer or more targeted records. Without such analysis, it is not possible to assess whether the magnitude of the paperwork burden is justified by commensurate benefits.

For these reasons, FDA's claimed benefits remain generalized and insufficiently bounded for purposes of PRA approval. While the objectives FDA identifies may be legitimate, the agency has not demonstrated that the specific scope and scale of the information collection it seeks to renew are necessary to achieve those objectives. Under the PRA, broad assertions of usefulness cannot substitute for evidence that the benefits of an information collection are proportional to the burdens it imposes.

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#### IV. Anecdotes Are Not Evidence of Proportional Utility

FDA and its supporters frequently point to anecdotal examples in which records assisted foodborne illness investigations or facilitated traceback during specific outbreaks. These examples are typically cited to demonstrate that traceability can work in practice and that access to records may help the agency reconstruct supply chains more quickly than in the past. While such anecdotes may illustrate the general concept of traceability, they do not establish that the current information collection, at its present scale, satisfies the PRA's requirements.

In many of the cited examples, the records that enabled traceback were **existing commercial documents**—such as invoices, bills of lading, shipping manifests, or internal tracking systems—produced and maintained for ordinary business purposes. In other cases, FDA benefited from **voluntary cooperation** by firms with sophisticated compliance systems, rather than from standardized, mandatory documentation imposed across the entire supply chain. These circumstances do not demonstrate the necessity of imposing additional, uniform recordkeeping obligations on all covered entities.

This distinction is critical because baseline traceability already exists in most commercial food distribution systems. The relevant PRA question is not whether some level of recordkeeping can support traceback, but whether the **incremental requirements imposed under FSMA Subpart S** materially improve outcomes beyond what existing records already provide. FDA has not shown that these incremental layers of documentation are responsible for the anecdotal successes it cites.

Moreover, isolated examples of successful traceback do not justify **universal and permanent documentation mandates**. Anecdotes, by their nature, highlight instances where a system functioned as intended, while obscuring cases where extensive recordkeeping did not meaningfully improve outcomes or where information gaps persisted despite compliance. The PRA requires evaluation of systemic utility, not selective illustration.

Anecdotal evidence also cannot establish **diminishing returns or optimal scale**. It does not answer how much documentation is enough, when additional records cease to improve response capability, or whether alternative approaches could achieve similar benefits with lower burden. Without such analysis, agencies risk assuming that more information is always better, even as marginal utility declines.

Accordingly, while anecdotal examples may establish the plausibility of traceability as a regulatory concept, they do not satisfy the PRA's evidentiary standard. To justify renewal of an information collection of this magnitude, FDA must demonstrate that the specific records required, and the volume at which they are collected, provide practical utility proportional to their cost. Anecdotes alone cannot carry that burden.

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#### V. Disproportionate Impact and Competitive Distortion

The paperwork burdens imposed by this information collection do not fall evenly across the regulated community. Large, vertically integrated firms are often able to amortize extensive documentation requirements as a fixed cost of doing business, spreading compliance overhead across high volumes, integrated supply chains, and dedicated compliance staff. Smaller and

independent operators, by contrast, must absorb the same requirements on a per-transaction basis, often without the scale, staffing, or technological infrastructure necessary to manage them efficiently.

As a result, paperwork functions as a **barrier to entry** and an **accelerant of consolidation**. Compliance costs that appear modest in isolation become prohibitive when layered onto routine, high-frequency transactions, discouraging new market entry and pressuring smaller firms to exit, merge, or contract. Over time, this dynamic reshapes markets not through competition on quality or safety, but through differential tolerance for administrative burden.

This outcome runs directly counter to a level playing field. CRF has consistently emphasized that regulatory regimes should not privilege incumbency or scale absent clear statutory direction. When compliance structures advantage firms best able to internalize bureaucratic cost, regulation ceases to be neutral and instead becomes a mechanism that selects winners and losers indirectly. The traceability recordkeeping regime at issue reflects precisely this concern.

FDA's burden estimates further understate the economic effects of the information collection by focusing narrowly on direct labor hours. They do not account for **opportunity costs**—the productive activity, investment, and innovation foregone when time and resources are diverted to compliance. Nor do they capture secondary effects such as reduced flexibility, delayed expansion, or the redirection of capital toward administrative systems rather than operational improvements.

When paperwork hours are translated into opportunity costs using CRF's established analytical framework, the magnitude of the burden becomes clearer. Even at the most conservative end of the range, billions of dollars in direct compliance costs correspond to multiple billions more in lost economic opportunity. At median or upper-bound estimates, the opportunity cost of this paperwork regime reaches into the tens of billions of dollars annually, reflecting suppressed productivity and constrained market participation.

These impacts are not incidental or transitory. They are **structural**, embedding higher costs into supply chains and ultimately into consumer prices. As compliance costs accumulate, they become part of the baseline cost of food production and distribution, contributing to affordability pressures that are borne by households regardless of whether the underlying paperwork produces commensurate public health benefits.

The competitive effects of this regime also have long-term implications for resilience and diversity in the food system. Concentration driven by regulatory burden reduces the number of independent actors, limits redundancy, and can increase systemic vulnerability—outcomes that run counter to the stated goals of food safety and supply chain security.

For these reasons, PRA review must account for competitive and affordability effects alongside administrative burden. The statute does not confine “burden” to timekeeping abstractions; it requires consideration of real-world economic impacts. Absent a demonstration that these competitive distortions are necessary and justified by proportional benefits, the information collection cannot be approved consistent with the PRA.

Accordingly, FDA's failure to address the disparate impacts of its recordkeeping requirements further underscores why renewal of this ICR, at its current scope and scale, is not warranted

without substantial revision and justification.

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## VI. Paperwork as a Substitute for Targeting and Enforcement

The structure of the traceability recordkeeping regime suggests that FDA is relying on **documentation density** as a primary means of managing enforcement uncertainty. By requiring extensive, uniform records across a broad universe of entities and transactions, the agency effectively shifts the burden of uncertainty from enforcement discretion to regulated parties. Rather than targeting specific risks, the system presumes that comprehensive documentation will compensate for limited ability to predict where contamination will occur.

Paperwork, however, cannot substitute for **risk-based targeting**. Effective food safety regulation depends on focusing regulatory attention on activities, products, and actors that present heightened risk, informed by data, inspection, and enforcement experience. Uniform documentation requirements applied regardless of risk profile dilute regulatory focus, generating large volumes of information that may obscure, rather than illuminate, the most significant safety concerns.

This problem is compounded by the absence of meaningful **tiering, exemptions, or differentiation** within the information collection. The recordkeeping obligations do not scale based on demonstrated risk, hazard severity, or compliance history. Instead, they scale primarily with transaction volume, capturing vast amounts of low-risk activity while offering no clear explanation for why such breadth is necessary to achieve traceback objectives.

The reliance on paperwork as a default solution reflects a broader administrative temptation to manage complexity **procedurally rather than substantively**. Faced with heterogeneous supply chains and uncertain risks, agencies often gravitate toward comprehensive documentation regimes because they are administratively simple to design and defend. Over time, this approach privileges process over outcomes, substituting volume of information for analytical precision.

CRF has observed this dynamic across multiple agencies and regulatory contexts. Whether in environmental regulation, healthcare administration, financial oversight, or transportation policy, expansive paperwork requirements are frequently used to compensate for unclear standards, diffuse accountability, or limited enforcement capacity. In each case, paperwork becomes a stand-in for regulatory judgment rather than a tool that meaningfully improves outcomes.

The consequence is not merely inefficiency, but institutionalization of inefficiency. As documentation requirements proliferate, agencies become invested in maintaining and expanding them, even in the absence of evidence that additional records improve performance. Regulated entities, in turn, devote increasing resources to compliance systems that do little to advance substantive policy goals.

Ultimately, this approach risks undermining food safety rather than strengthening it. When regulatory effort is consumed by managing paperwork volume, fewer resources are available for inspections, targeted interventions, and corrective action. By treating documentation as a substitute for targeting and enforcement, FDA entrenches a system that prioritizes administrative completeness over effective risk reduction—an outcome inconsistent with both sound regulation

## VII. Recommendations for OMB and FDA

Given the scale and systemic impact of the proposed information collection, CRF urges the Office of Management and Budget to condition any approval on a clearer and more rigorous demonstration of **marginal utility**. FDA should be required to identify which specific data elements materially improve traceback outcomes, how frequently those elements are used in practice, and whether incremental layers of documentation produce benefits commensurate with their cost. Without such a showing, PRA approval would rest on aspiration rather than evidence.

CRF further recommends that FDA explore **tiered, risk-based, or size-sensitive alternatives** to the current uniform documentation regime. Information collection should be calibrated to demonstrated risk, hazard severity, and supply-chain role, rather than applied indiscriminately across all entities and transactions. Tailoring requirements in this manner would better align paperwork burden with public health benefit and reduce unnecessary compliance costs for lower-risk actors.

FDA should also be encouraged to rely more explicitly on **existing commercial records** where those records already capture relevant traceability information. Many firms maintain detailed documentation for inventory management, logistics, and quality control independent of regulatory mandates. Leveraging these records, rather than imposing duplicative or prescriptive formats, would preserve traceback capability while minimizing incremental burden.

Before extending or expanding economy-wide requirements, FDA should pursue **pilot-based validation** of traceability approaches. Targeted pilots can test which records are actually used during outbreak investigations, identify points of diminishing returns, and evaluate whether alternative systems deliver comparable results with lower burden. Such validation would provide an empirical basis for any broader information collection.

CRF also recommends that FDA and OMB commit to **periodic burden retrospectives** tied to actual outbreak outcomes. These reviews should assess whether the information collected was accessed, how it influenced agency response, and whether it measurably improved public health outcomes. Retrospectives would help ensure that paperwork requirements remain justified over time and are adjusted as conditions and evidence evolve.

Finally, CRF emphasizes that PRA approval should not be treated as an **automatic or routine renewal**. The PRA assigns OMB an active gatekeeping role, particularly where information collections impose substantial and recurring burdens. Exercising that role here would reinforce the statute's purpose, promote regulatory discipline, and ensure that documentation requirements remain proportionate, targeted, and grounded in demonstrated practical utility.

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## Conclusion

CRF reiterates its support for effective food safety regulation and for FDA's responsibility to respond rapidly and competently to foodborne illness outbreaks. Timely traceback, informed enforcement, and coordinated response efforts are legitimate and important public health

objectives. Nothing in these comments should be construed as minimizing the seriousness of food safety risks or the agency's role in addressing them.

At the same time, traceability must be understood as a **means**, not an end in itself. Paperwork is a regulatory tool, not a policy outcome. The existence of records, standing alone, does not ensure improved safety, and the accumulation of documentation cannot substitute for clarity, targeting, and sound regulatory judgment. Under the PRA, information collection must be justified by demonstrated practical utility, not by generalized appeals to programmatic goals.

The Paperwork Reduction Act was enacted to prevent precisely the kind of unbounded documentation regime at issue here. Congress recognized that unchecked paperwork accumulation imposes real economic costs, distorts behavior, and diverts resources away from productive and socially beneficial activity. When information collections are renewed without rigorous scrutiny of necessity and proportionality, the PRA's protections are eroded.

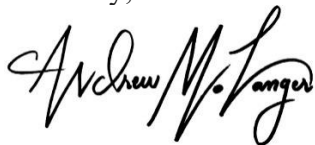
CRF is particularly concerned that repeated renewal of this ICR risks entrenching administrative workarounds in place of substantive solutions. Over time, paperwork can become a proxy for enforcement strategy, masking underlying issues in risk prioritization and regulatory design. Once institutionalized, such regimes are difficult to unwind, even when evidence of marginal benefit remains thin.

These concerns are inseparable from broader public interests in **affordability, competition, and proportionality**. Extensive paperwork requirements embed costs throughout the food supply chain, with disproportionate impacts on smaller and independent operators and downstream effects on consumer prices. Regulatory policy that unintentionally accelerates consolidation or suppresses market participation undermines resilience and public confidence.

Accordingly, CRF urges the Office of Management and Budget to exercise its gatekeeping authority under the PRA in a meaningful and disciplined manner. OMB review should require FDA to demonstrate, with specificity and evidence, that the scope and scale of the proposed information collection are necessary and that its benefits are proportional to its burdens.

CRF remains committed to constructive engagement with FDA and OMB in pursuit of lawful, disciplined, and economically grounded regulation. By insisting on proportionality, practical utility, and analytical rigor, the PRA can function as Congress intended—protecting both public health and the economic foundations that support a safe, resilient, and affordable food system.

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