The hidden data gap behind recurring drug shortages

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The pharmaceutical supply chain, a complex global network, often operates with opaque data, making rapid identification of manufacturing sites and their specific roles challenging for regulators. This lack of granular detail can impede swift responses to drug shortages, quality issues, or public health emergencies.
The US Food and Drug Administration (FDA) has now proposed a rule to update and modernize its drug manufacturing establishment registration requirements, aiming to enhance transparency and improve regulatory oversight. This move intends to provide the agency with more precise, facility-specific information, moving beyond the current broad data collection.

KEY TAKEAWAYS

- The Pivot: The FDA will require facility-specific data and unique facility identifiers (UFIs) for drug manufacturing registrations, replacing less detailed site-level information.
- The Data: All registered establishments must provide a UFI from a D&B DUNS number, linking each facility to a specific physical address and operational details.
- The Action: Clinicians should anticipate improved supply chain visibility and potentially faster responses to drug shortages, though direct immediate changes to prescribing are unlikely.

The current regulatory framework for drug manufacturing registration, largely established under the Federal Food, Drug, and Cosmetic Act (FD&C Act), mandates that all establishments involved in the manufacture, preparation, propagation, compounding, or processing of drugs for introduction into interstate commerce register annually with the FDA. This system, while foundational, has grown increasingly complex and, at times, inefficient due to the evolving global nature of pharmaceutical production. The existing regulations, codified in 21 CFR Part 207, often collect information at a broad organizational level, rather than focusing on the granular, facility-specific details necessary for modern supply chain management and risk assessment. This has led to situations where the FDA struggles to quickly identify the precise location and specific activities of every entity contributing to a drug's production, from active pharmaceutical ingredient (API) synthesis to final packaging.1

The proposed rule, published in the Federal Register, seeks to amend 21 CFR Part 207 by requiring more detailed and standardized information from drug manufacturing establishments. The core of this modernization effort centers on the mandatory use of a unique facility identifier (UFI) for each registered establishment. Specifically, the FDA proposes that the Data Universal Numbering System (DUNS) number, issued by Dun & Bradstreet (D&B), will serve as the UFI. This requirement means every facility involved in drug manufacturing, whether domestic or foreign, must obtain and submit a DUNS number as part of its annual registration. This change aims to create a consistent, globally recognized

identifier for each physical manufacturing site, allowing the FDA to link specific addresses and operational details to each registration.1

What the FDA actually wants

The FDA's proposal mandates that registrants submit the UFI for each establishment. This UFI must be obtained from a D&B DUNS number, which is a nine-digit identifier assigned to a physical location of a business. The agency has explicitly stated that it will not accept registrations without a valid UFI, or if the UFI provided does not correspond to the physical address of the establishment being registered. This strict enforcement mechanism ensures data integrity and prevents the use of generic or incorrect identifiers. The DUNS system, already widely used in global commerce, provides a standardized way to identify businesses, offering a level of detail and verification that the current system lacks.1

Beyond the UFI, the proposed rule also seeks to clarify and expand the types of information required during registration. Establishments must provide a comprehensive list of all drug products manufactured, prepared, propagated, compounded, or processed at their facility. This includes details such as the proprietary name, established name, dosage form, strength, and route of administration for each product. For human drugs, registrants must also specify the applicable drug product listing number. This level of detail allows the FDA to better understand the scope of operations at each facility and to track specific products through their manufacturing lifecycle.1

The rule also clarifies the definition of what constitutes a “manufacturing establishment” for registration purposes. It specifies that contract manufacturing organizations (CMOs) and contract research organizations (CROs) involved in certain drug manufacturing activities, such as packaging, labeling, or testing, must also register. This broadens the scope of oversight to include entities that play critical, but sometimes less visible, roles in the drug supply chain. The FDA intends for this expanded definition to close potential gaps in regulatory visibility, ensuring that all significant contributors to drug production are accounted for and subject to appropriate oversight.1

The numbers and the rationale

The FDA’s rationale for these changes is rooted in several key objectives. First, the agency aims to enhance its ability to identify and respond to drug shortages. By having precise, facility-specific data, the FDA can more quickly pinpoint the source of a shortage, assess its impact, and work with manufacturers to mitigate it. The current system, with its less granular data, often requires additional investigative steps to determine which specific facility is responsible for a particular product, delaying intervention. This modernization is projected to reduce the time spent on such investigations by an average of 25%, according to internal FDA estimates, potentially saving critical weeks during a supply crisis.1

Second, the proposed rule seeks to improve the FDA's ability to conduct risk-based inspections. With a clearer understanding of each facility's operations and the products it handles, the agency can better prioritize inspections, focusing resources on sites that pose the highest risk to public health. This targeted approach is expected to increase the efficiency of FDA inspections by 15%, allowing for more frequent oversight of high-risk facilities and a more effective allocation of limited regulatory resources. The use of UFIs will also streamline data analysis, enabling the FDA to identify patterns and potential vulnerabilities across the global supply chain more effectively.1

Third, the FDA intends to improve its communication with manufacturers during emergencies. When a public health crisis arises, such as a contamination event or a widespread quality issue, having accurate and up-to-date contact information linked to specific facilities is paramount. The proposed rule requires registrants to provide current contact

information for each establishment, including a primary contact person and an emergency contact. This ensures that the FDA can reach the appropriate personnel quickly, facilitating rapid information exchange and coordinated responses. This is particularly relevant for foreign manufacturers, where communication can be complex and time-sensitive.1

The agency also highlights the benefits of aligning its registration requirements with international standards. Many other regulatory bodies globally already utilize unique identifiers for manufacturing sites, and the adoption of DUNS numbers by the FDA will foster greater interoperability and data sharing among international regulators. This harmonization can simplify compliance for multinational pharmaceutical companies and improve global supply chain transparency. The European Medicines Agency (EMA), for example, has been moving towards similar granular data requirements for manufacturing sites, making this FDA proposal a step towards global regulatory convergence.1

Where it falls short

While the proposed rule offers clear advantages, its implementation poses several challenges. Small and medium-sized enterprises (SMEs), particularly those operating in developing countries, may face difficulties in obtaining and maintaining DUNS numbers. The process, while generally straightforward, can involve administrative hurdles and potential costs, which could disproportionately affect smaller manufacturers with limited resources. The FDA has acknowledged this concern, stating it will provide guidance and support, but the practical impact on global compliance remains to be seen. Some critics argue that relying solely on a proprietary system like DUNS, rather than a publicly managed identifier, introduces a single point of failure and potential cost burden for registrants.1

Another potential limitation involves data accuracy and maintenance. While the UFI aims to standardize identification, the onus remains on manufacturers to ensure that all submitted information, including product lists and contact details, is accurate and updated annually. Inaccurate or outdated data could undermine the very purpose of the modernization effort, leading to continued challenges in supply chain visibility. The FDA will need robust enforcement mechanisms and clear guidelines for data submission to ensure the integrity of the new system. The agency has not yet detailed the specific penalties for non-compliance with the UFI requirement, which could be a critical factor in ensuring adherence.1

The rule also does not explicitly address the real-time tracking of drug products, focusing instead on establishment registration. While improved facility data is a step forward, it does not provide immediate visibility into the movement of specific drug batches through the supply chain. This limitation means that while the FDA will know where a drug is manufactured, it may still face challenges in tracing a contaminated batch once it has left the manufacturing site and entered distribution. Future regulatory efforts may need to consider more advanced serialization and tracking technologies to achieve true end-to-end supply chain visibility. Still, this foundational data improvement is a necessary precursor to such advanced systems.1

The proposed rule represents a significant step towards modernizing the FDA's oversight of drug manufacturing. By mandating unique facility identifiers and requiring more detailed registration information, the agency aims to enhance its ability to manage drug shortages, conduct risk-based inspections, and respond to public health emergencies more effectively. The success of this initiative will depend on robust implementation, clear guidance for manufacturers, and ongoing efforts to ensure data accuracy and compliance across the global pharmaceutical landscape. The next step involves public comment and potential revisions before finalization, but the direction of travel is clear: more data, more transparency, and tighter control over who makes our medicines.

CLINICAL IMPLICATIONS

This proposed FDA rule, while seemingly administrative, carries tangible implications for clinicians. Improved supply chain visibility means a more resilient drug supply, directly impacting patient care by reducing the frequency and duration of drug shortages. GPs often bear the brunt of these shortages, navigating complex substitutions and managing patient anxiety, so any measure that stabilizes supply is welcome.

The enhanced data collection should also empower the FDA to respond more rapidly to quality control issues or contamination events. Knowing precisely which facility produced a problematic batch allows for quicker recalls and targeted interventions, minimizing patient exposure to substandard or harmful products. This translates to greater confidence in the integrity of the medicines we prescribe daily.

But the success hinges on global compliance, particularly from foreign manufacturers. If smaller international facilities struggle with the new UFI requirements, it could paradoxically lead to temporary supply disruptions as they navigate the updated system. The FDA must ensure accessible support and clear communication to prevent unintended consequences for the global drug supply, which directly affects European markets through parallel imports and global manufacturing dependencies. Clinicians should remain aware of these potential short-term frictions during the transition.

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