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Alliance for Pharmacy Compounding

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Docket No. FDA-2024-N-3762-0006

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Comment on Proposed Information Collection—Compounding Outsourcing Facilities Survey

To Whom it May Concern:

On behalf of the Alliance for Pharmacy Compounding, we appreciate the opportunity to submit comments in response to the proposed information collection related to the FDA's effort to better understand the operational, economic, and regulatory challenges facing 503B outsourcing facilities.

We commend the agency for recognizing that outsourcing facilities are a critical yet underutilized component of the U.S. pharmaceutical manufacturing ecosystem—especially in mitigating persistent drug shortages and helping to rebuild domestic production capacity.

This proposed survey is a welcome and important step toward a more responsive and resilient drug supply chain—but it must be properly scoped to ensure meaningful, actionable results.

1. Support for the Survey's Intent—With Practical Recommendations

We support FDA's plan to collect data on the outsourcing facility landscape. However, we offer the following suggestions to strengthen the survey's utility and increase response completion:

Realistic Time Estimates: FDA has indicated that the revised survey will contain 10 questions and take only 30 minutes to complete, an estimate that is likely **significantly underestimated**. Several of the proposed questions (e.g., "What financial and operational considerations inform outsourcing facility business decisions?") are highly complex and multifaceted. Answering these accurately requires detailed operational, economic, and regulatory disclosures that cannot reasonably be completed in three minutes per question.

For example, a full response would require information on:

- R&D costs for new compounded drug development;
- Proportion of operations involving bulk vs. finished API;

- Use of sterile vs. nonsterile compounding practices;
- Starting material sourcing strategies;
- Quality testing and cost burdens under CGMP;
- Response planning for drug shortage list changes; and
- The current status and uncertainty surrounding the 503B Bulk Substances List.

APC recommends FDA revise the estimated completion time to 60–90 minutes and communicate that to prospective respondents. Without a realistic expectation of time burden, we believe many participants will begin but not complete the survey.

Survey Platform Functionality: The survey platform should allow pause-and-resume functionality so that respondents can complete their submissions across multiple sittings. The invitation should also suggest completing the survey outside of standard business hours to increase thoughtful participation by senior operational staff.

Stratified Analysis: We encourage the agency to segment survey results by facility size, product type (sterile vs. nonsterile), and bulk vs. finished API usage. These distinctions are critical to accurately assess the capacity, constraints, and readiness of outsourcing facilities.

2. The Untapped Potential of 503B Outsourcing Facilities

503B outsourcing facilities are FDA-registered, CGMP-compliant, and routinely inspected. During the COVID-19 emergency, many 503Bs delivered sterile medications at scale to hospitals and health systems when traditional manufacturers could not.

That same capability exists today and can be harnessed to:

- Fill persistent gaps in the generic drug market;
- Supply medications for which no FDA-approved manufacturer currently exists; and
- Respond rapidly to public health and supply chain emergencies.

Many of the drugs most vulnerable to shortage are:

- Generic medications approved more than 40 years ago;
- Low-profit or medically necessary injectables; or

Emergency-use drugs required in anesthesia, critical care, and oncology.503Bs have the infrastructure but often lack a regulatory framework or clear economic pathway to respond at scale. The survey should help quantify these missed opportunities.

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3. Acknowledge Economic Realities and Natural Market Limits

We urge FDA to account for the **built-in economic disincentives** that naturally limit outsourcing facilities' ability to displace FDA-approved manufacturers.

- Most 503B products are **not reimbursed** by PBMs or Medicare Part D.
- Outsourcing facilities **lack the economies of scale** to compete long-term.
- Production often ceases when commercial supply is restored, even after significant investment in development and validation.

These factors serve as natural market boundaries and reinforce that 503Bs are not trying to replace conventional manufacturers, but to support the system when it fails.

4. Conclusion

FDA's proposed survey has the potential to yield meaningful insights that can inform future policy decisions. But to do so, it must:

- Accurately reflect the **time and complexity** of the questions being asked;
- Enable thoughtful, uninterrupted participation; and
- Be designed to capture the **full scope of economic and regulatory barriers** that prevent outsourcing facilities from stepping in during drug shortages.

We would welcome the opportunity to assist the agency in refining the survey design or serving as a conduit to gather high-quality input from APC's 503B members.

Thank you for your commitment to understanding the critical role outsourcing facilities can play in a stronger, more resilient drug supply chain.

Sincerely,

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