



Healthcare Distribution Alliance

HEALTH DELIVERED

November 5, 2024

**FILED BY ELECTRONIC SUBMISSION**

**Docket No. FDA-2024-N-3675**

[PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov)

**Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Pharmaceutical Distribution Supply Chain; Drug Supply Chain Security**

Dear Associate Commissioner Roth,

The Healthcare Distribution Alliance (HDA), National Association of Chain Drug Stores (NACDS), and National Community Pharmacists Association (NCPA) thank the Food and Drug Administration (FDA) for the opportunity to submit comments to its “Agency Information Collection Activities; Proposed Collection; Comment Request; Pharmaceutical Distribution Supply Chain; Drug Supply Chain Security [DSCSA]”<sup>1</sup> (the “Proposed Collection”), which seeks comment on FDA’s estimates of DSCSA reporting and recordkeeping related to the traceability and verification requirements.

HDA represents primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS’ member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries.

The National Community Pharmacists Association (NCPA) represents America’s community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ more than 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America’s most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

We collectively request that FDA revise its numbers in Table 1 regarding expected requests from trading partners under FDA’s “Waivers, Exceptions, and Exemptions” (“WEE”) process. Table 1 states that FDA only expects 20 respondents for a WEE annually, which we believe is a significant underestimate based on trading partner submissions this year.<sup>2</sup>

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<sup>1</sup> 89 Fed. Reg. 72848 (Sept. 6, 2024), *available at* <https://www.federalregister.gov/documents/2024/09/06/2024-20064/agency-information-collection-activities-proposed-collection-comment-request-pharmaceutical>.

<sup>2</sup> We understand that FDA may have drafted this Proposed Collection prior to the influx of WEE requests at the end of this summer and early fall.

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Specifically, prior to FDA's recent grant of additional exemptions for eligible trading partners on October 9th,<sup>3</sup> FDA had stated that trading partners should submit their own individual requests should those trading partners believe they may not be able to comply with upcoming requirements under the DSCSA. In response to FDA's statement, it was widely understood that several pharmacies and distributors submitted WEE requests to be relieved of final DSCSA requirements due in part to the lack of readiness of upstream trading partners. FDA indicated at HDA's Traceability Seminar this year that it had received hundreds of WEEs as of the end of August.

Although we are aware that there were more than 20 WEE requests this year, the public is not privy to the exact number. However, the requests FDA received this year provided the Agency with a sense of how many products and/or transactions may have needed to be subject to individual WEEs and may have contributed to the Agency's use of own authority to issue additional exemptions for eligible trading partners. We ask that FDA revise the Table 1 numbers to reflect the WEEs expected for this year and factor in future individual WEE requests due to supply chain readiness of upstream trading partners in future estimates.

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We thank FDA for this opportunity to provide comments on the Proposed Collection. If you have any questions, please contact Kala Shankle, Vice President, Regulatory Affairs ([kshankle@hda.org](mailto:kshankle@hda.org)), Sara Roszak, Senior Vice President, Health & Wellness Strategy & Policy, National Association of Chain Drug Stores ([sroszak@nacds.org](mailto:sroszak@nacds.org)), and Ronna Hauser, Senior Vice President, Policy & Pharmacy Affairs ([ronna.hauser@ncpa.org](mailto:ronna.hauser@ncpa.org)).

Sincerely,

/s/ Kala Shankle

Vice President, Regulatory Affairs  
Healthcare Distribution Alliance



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<sup>3</sup> We thank FDA for its recent exemptions, because they recognize the need for a phased approach to stabilize trading partner data exchange and forestall the potential for unnecessary disruptions in the supply chain that could have occurred at the end of November.