APhA
American Pharmacists Association

December 7, 2022

Jill Furman, JD
Acting Director
Office of Compliance
Center for Drug Evaluation and Research

CAPT Connie Jung, PhD, RPh
Senior Advisor
Office of Compliance/ODSIR
Center for Drug Evaluation and Research

RE: Request for Enforcement Discretion for DSCSA Small Business Dispensers

Submitted via email

Dear Ms. Furman and Dr. Jung:

The American Pharmacists Association (APhA) requests that the Food and Drug Administration (FDA) urgently announce and exercise enforcement discretion for small business dispenser compliance with the requirements related to the Drug Supply Chain Security Act (DSCSA) under section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). APhA strongly supports the purpose and goals of the DSCSA to enhance the safety and security of the pharmaceutical distribution supply chain. However, because of FDA's failure to meet the statutory deadlines related to standards and small business dispenser requirements, there is no alternative for FDA other than to provide enforcement discretion to enable FDA to complete the assessments and the statutorily required follow up before providing small business dispenser guidance.

APhA leads and advances the pharmacy profession. APhA represents pharmacists, pharmacy technicians, and student pharmacists in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. APhA's members strive to improve medication use, advance patient care, and enhance public health.

Small business dispenser impact assessment overdue

Pursuant to sections 582(g)(2) and (3) of the FD&C Act, a small dispenser assessment shall be conducted no later than 18 months after the guidance in section 582(h) is finalized. According to section 582(g)(3)(A), the small business dispenser assessment was required to be completed no later than 8 ½ years after the date of enactment of DSCSA, which was November 23, 2013. According to sections 582(g)(2)(D)(ii) and (iii), FDA was also required to give 30 calendar days of public comment on the assessment and to hold a public meeting no later than 180 calendar days after receiving the final assessment from the contractor conducting the assessment. Congress added these timeframes to ensure that the assessment adequately assess the impact of the "final guidance required under subsection (h)," which includes all the guidances at section 582(h) (2), (3), and (4), in order to determine the cost and burdens of practical implementation based on the final guidance provided by FDA. However, because FDA has not finalized the guidance at subsection (h) and has not conducted the small business dispenser assessment within the 8 ½ years of enactment, the small business dispenser assessment will not be able to be conducted and completed with enough time for the required public comment period and public meeting. In addition, there will not be adequate time for affected dispensers to implement of any of the alternative methods for compliance that have yet to be identified pursuant to section 582(g)(2)(B).

Announce enforcement discretion ASAP

The requirements in section 582(g) for interoperable, electronic tracing of products at the package level go into effect in less than 11 months. All trading partners are actively working to be ready for the November 27, 2023, compliance date. Although it may seem that there is plenty of time for FDA to share whether it will provide enforcement discretion, this not the case. As small businesses, under the stress of the testing, immunizing and treatment for COVID-19 and the triple-demic, drug shortages, and financial and staffing challenges, they must use their precious resources and time very wisely and efficiently. They do not have the time or resources to guess or invest in what might be required upon completion of the small business assessment. Because FDA knows now that the statutory steps will not be completed with adequate time for small business to implement the requirements by November 27, 2023, we urge FDA to immediately issue guidance on enforcement discretion for the appropriate sections so these dispensers can focus on essential patient care and not waste precious time, personnel, and financial resources.

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Conclusion

APhA appreciates FDA's ongoing efforts in developing guidance and standards to assist pharmacists and pharmacies in complying with DSCSA's requirements to improve the safety and security of the drug supply chain. Thank you for your consideration of our urgent request. We look forward to hearing back from you soon. If you have any questions or require additional information, please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Ilisa BG Bernstein

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Interim Executive Vice President and CEO
American Pharmacists Association

cc: Docket No. FDA-2014-D-1981-0019