February X, 2023

Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

RE:  Request for Enforcement Discretion for DSCSA Small Business Dispensers

Dear Food and Drug Administration staff:

As a pharmacy with 25 or fewer full-time employees, I request that FDA announce that you will exercise enforcement discretion for the DSCSA requirements that will go into effect in November 2023 for small business dispensers. My pharmacy will need additional time to implement any alternative methods for compliance that FDA has not yet identified for small business dispensers. It will be very difficult for my pharmacy to set up compliant systems and processes without further direction and guidance from FDA.

As you know, pharmacists and pharmacies have been busy during the pandemic, with testing, immunizing, and treatments for COVID-19. In addition, there is added focus on the tripledemic we are experiencing this season with respiratory viruses, in addition to drug shortages, and financial and staffing challenges. As a small business, our resources are very limited, and our time must be spent efficiently. Until there is greater certainty for how to comply with these new requirements, many dispensers in the same situation as me are reluctant to invest already limited resources or consider what they will do to meet the requirements, including whether they will rely on their wholesalers for implementation.

 I urge FDA to delay the November 27, 2023 effective date for small business dispensers and issue guidance on enforcement discretion for the appropriate sections of this law as soon possible. This will enable my pharmacy to focus on what is most important for us as frontline healthcare professionals --- providing patients with the essential care they need during multiple public health challenges and beyond.

Thank you for your consideration of this request.

Sincerely,

[Insert pharmacist name and contact information]