*Submitted electronically to:* www.regulations.gov

February 16, 2024

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket; Request for Information and Comments [Docket No. FDA–2023–N–4806]**

Dockets Management Staff:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to FDA on its *Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket* Request for Information and Comments.

NCPA represents America's community pharmacists, including 19,400 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 represent a $94 billion healthcare marketplace, employ 230,000 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.

In response to FDA's RFI inquiring how stakeholders are using the stabilization period, NCPA has heard from its members that if they receive EPCIS data from wholesalers, they are getting incomplete EPCIS data because the wholesalers in turn are getting incomplete EPCIS data from manufacturers, if it is sent. This is impeding a more thorough analysis of independent pharmacy readiness to DSCSA, and many independent pharmacies are waiting to assess their need for a compliance solution until they start getting complete EPCIS data.

Our concerns echo that of the Healthcare Distribution Alliance (HDA), who has indicated in a recent comment letter to FDA that both manufacturers and distributors are having issues with sending complete and accurate product identifiers in TI in an EPCIS3 file, and both groups of stakeholders do not know when this will be resolved. Wholesalers are also having difficulty getting clarity from manufacturers about the latter's ability to meet their interoperability obligations.

NCPA has serious concerns that the supply chain stakeholders upstream of pharmacies do not have the systems and processes in place to provide the data required to meet the November 27, 2024 enforcement deadline for DSCSA's interoperability provisions. This in turn affects pharmacy readiness downstream. Given that interoperability data is required for DSCSA-covered products, NCPA is concerned that drug shortages could occur after November 27.

NCPA appreciates the opportunity to share with FDA our comments on the *Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket* Request for Information and Comments. Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association