APhA
AMERICAN PHARMACISTS ASSOCIATION
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Submitted electronically to Connie.jung@fda.hhs.gov

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U.S. Food and Drug Administration
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RE: Request for Exercise of Enforcement Discretion for Certain Dispenser Requirements Under the Drug Supply Chain Security Act

Dear Dr. Jung:

As you might recall, on August 10, 2020, on behalf of our pharmacy organization colleagues, we forwarded to you the attached May 22, 2020 letter to Dr. Woodcock requesting that the Food and Drug Administration (FDA) exercise enforcement discretion for certain product identifier and verification requirements of the Drug Supply Chain Security Act (DSCSA) due to the COVID-19 public health emergency.

Specifically, we requested that:

1. FDA exercise enforcement discretion and not take action against a dispenser for engaging in transactions involving a product purchased from an authorized trading partner that is not encoded with an applicable product identifier, (pursuant to section 582(d)(2)), and is not otherwise suspect or illegitimate until at least November 27, 2021; and

2. FDA exercise enforcement discretion and not take action against a dispenser who does not conduct an investigation to verify whether the lot number of a suspect product corresponds with the lot number for such product (pursuant to section 582(d)(4)(A)(ii)(I)) and verify that the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for such product (pursuant to section 582(d)(4)(A)(ii)(II)), at least until November 27, 2021.

APhA members and pharmacists across the country have been asking for this reprieve from the DSCSA requirements set to take effect this November so that they can focus their attention and efforts on COVID-19 testing, vaccination, and continued care of their patients. Without enforcement discretion of these DSCSA requirements, there will be significant disruptions to pharmacy operations that might impact patient access to medications. This is unacceptable during a pandemic.

Given that the November 2020 implementation date of these DSCSA requirements is fast approaching, APhA urges the FDA to promptly issue guidance on enforcement discretion for sections 582(d)(2) and 582(d)(4)(A)(ii)(I)-(II) until at least November 27, 2021 so that pharmacists can focus on the COVID-19 response.

Thank you for your consideration of our urgent request. We look forward to hearing back from you soon.

Sincerely,

Karin L. Bolte

Karin L. Bolte, J.D.
Director, Health Policy

cc:
Donald Ashley, Esq, Director, Office of Compliance, CDER, FDA
Patrizia Cavazzoni, M.D., Deputy Director for Operations, CDER, FDA