



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



APhA

AMERICAN PHARMACISTS ASSOCIATION



Submitted electronically to stephen.hahn@fda.hhs.gov

October 19, 2020

Dr. Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Urgent Request for Exercise of Enforcement Discretion for Certain Dispenser and Wholesale Distributor Requirements Under the Drug Supply Chain Security Act

Dear Dr. Hahn:

We are writing to request your **urgent** attention for FDA to provide relief from certain dispenser and wholesale distributor requirements under the Drug Supply Chain Security Act (DSCSA) that go into effect on November 27, 2020. Without enforcement discretion for these requirements we fear that there will be significant supply chain disruptions in our nation's drug supply. Together, the members of our organizations --- the American Pharmacists Association (APhA), American Society of Health-System Pharmacists (ASHP), Healthcare Distribution Alliance (HDA), National Alliance of State Pharmacy Associations

(NASPA), National Association of Chain Drug Stores (NACDS), and National Community Pharmacists Association (NCPA) --- our members make up a significant portion of the dispensers and wholesale distributors that DSCSA impacts.

On May 22, 2020, the dispenser organizations on this letter (APhA, ASHP, NACDS, NASPA, and NCPA) sent a letter to Dr. Woodcock requesting that the FDA exercise enforcement discretion for certain product identifier and verification requirements of the DSCSA due to the COVID-19 public health emergency. (See attached.)

Specifically, the organizations 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.

On April 24, 2020, HDA sent a letter to Dr. Woodcock and members of the Center for Drug Evaluation and Research's (CDER) senior leadership, requesting that FDA extend and revise the current Enforcement Discretion Guidance as to saleable returns verification and certain related requirements. Specifically, the HDA urged FDA to issue, as soon as possible, an Enforcement Discretion Guidance containing the following elements:

1. Extend the existing enforcement discretion for wholesale distributors at least until May 27, 2021.
2. Encourage trading partners to continue work on building capability to electronically verify saleable returns.
3. Establish a "soft launch" to begin electronic verification of saleable returns by no later than May 27, 2021.
4. Additional elements designed to support continuation of trading partners' diligent efforts to develop and implement verification systems over the next year despite the significant limitations posed by the COVID-19 public health emergency and the verification requirement's implementation complexities.

Dispensers and wholesale distributors across the country have been asking for this reprieve from the DSCSA requirements set to take effect next month so that they can focus their attention and efforts to address the COVID-19 pandemic, including testing and vaccinations as well as continued care of patients. Without enforcement discretion of these DSCSA requirements, there could be significant disruptions to pharmacy and wholesale distribution operations that could impact patient access to medications. This is unacceptable during a pandemic.

This request's immediacy is not overstated. If they haven't already done so, within days and without certainty that FDA will grant these requests, many supply chain members must perform substantial modifications to operations, procedures and staffing to allow the "lead time" needed to fully establish compliance by November 27. Such efforts may further strain dispensers and wholesale distributors that are already stretched thin by the pandemic public health emergency.

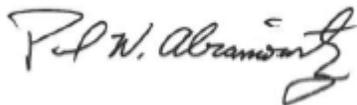
Given that the November 27, 2020 implementation date of these DSCSA requirements is fast approaching, we urge the FDA to immediately issue guidance on enforcement discretion for sections noted above so that dispensers and wholesale distributors can focus on the COVID-19 response.

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

Sincerely,



Scott Knoer, PharmD, MS, FASHP
Executive Vice President and CEO
American Pharmacists Association



Paul W. Abramowitz, PharmD, ScD (Hon), FASHP
Chief Executive Officer
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Chester "Chip" Davis, Jr.
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Steven C. Anderson, FASAE, IOM, CAE
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Rebecca Snead, RPh
Executive Vice President and CEO
National Alliance of State Pharmacy Associations



B. Douglas Hoey, RPh, MBA
Chief Executive Officer
National Community Pharmacists Association

Attachments:

- 1) Letter to Dr. Janet Woodcock from APhA, ASHP, NACDS, NASPA, NCPA, "Request for Exercise of Enforcement Discretion for Certain Dispenser Requirements Under the Drug Supply Chain Security Act." May 22, 2020
- 2) Letter to Dr. Janet Woodcock, Dr. Doug Throckmorton, Donald Ashley, Dr. Leigh Verbois, and Dr. Connie Jung from HDA, "Request for Additional Exercise of Enforcement Discretion as to Verification of Saleable Returned Drug Products." April 24, 2020.

Cc: Stacy Amin, JD
Douglas C. Throckmorton, MD
Peter Marks, MD, PhD
Donald D. Ashley, JD
Leigh Verbois, PhD
Connie Jung, RPh, PhD
Mary Malarkey