



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



APhA

AMERICAN PHARMACISTS ASSOCIATION



pharmacists advancing healthcare®



Submitted electronically to janet.woodcock@fda.hhs.gov

May 22, 2020

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 5I, Room 6133
Silver Spring, MD 20993

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

Dear Director Woodcock:

The National Association of Chain Drug Stores (“NACDS”), American Pharmacists Association (“APhA”), American Society of Health-System Pharmacists (“ASHP”), National Alliance of State Pharmacy Associations (“NASPA”), and National Community Pharmacists Association (“NCPA”) appreciates the Food and Drug Administration’s (“FDA’s”) recent guidance on exemptions and exclusions from certain requirements under the Drug Supply Chain Security Act¹ during the current public health emergency.² While the guidance is helpful, we submit this letter to further request that the FDA exercise enforcement discretion for certain product identifier and verification requirements in sections 582(d)(2) and 582(d)(4)(A)(ii)(I)-(II) of the Food, Drug and Cosmetic Act (“FDC Act”), which were established by the DSCSA. This action is crucial to maintain the dispenser community’s focus

¹ Public Law No. 113-54, Title II of the Drug Quality and Security Act.

² FDA, *Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency* (Apr. 2020), available at <https://www.regulations.gov/document?D=FDA-2020-D-1136-0009>.

during the current and unprecedented public health emergency caused by the 2019 Novel Coronavirus in which our members are engaged on the front lines.

Specifically, we request that:

1. FDA exercise enforcement action 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.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

APhA represents our nation's pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, specialty pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services. Please visit www.pharmacist.com.

ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization's nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, www.ashp.org, or its consumer website, www.SafeMedication.com.

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

NCPA represents America's community pharmacists, including 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services ("LTC") and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings.¹ Together, our members represent a \$76 billion healthcare marketplace, employ approximately 250,000 individuals, and provide an expanding set of healthcare services to millions of patients every day.

The DSCSA added section 582(d)(2) of the FDC Act, which requires dispensers to, beginning 7 years after the enactment date of the DSCSA, only engage in transactions with pharmaceutical products that have the DSCSA-compliant product identifier. Pursuant to 582(d)(4)(A)(i), in determining whether a suspect product is illegitimate, dispensers must promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product. The DSCSA also added section 582(d)(4)(A)(ii)(I)-(II) of the FDC Act, which requires dispensers, in conducting such an investigation and beginning 7 years after the enactment date of the DSCSA, to verify whether the lot number of a suspect product corresponds with the lot number for such product. More so, starting on that date dispensers must 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. Congress enacted the DSCSA on November 27, 2013. Thus, these dispenser requirements go into effect November 27, 2020. We request the FDA issue timely enforcement discretion in guidance that addresses FDA's compliance policy for these requirements.

We strongly support the purpose and goals of the DSCSA and dispensers across the supply chain are working to implement systems to comply by the statutory deadline. However, the current public health emergency has significantly disrupted the entire drug supply chain and challenges our members' abilities to conduct "business as usual." Specifically, during this unprecedented public health emergency our members are working tirelessly to meet the healthcare needs of their patients and to help to relieve the strain on other healthcare providers. Pharmacies also are faced with supply issues, staffing concerns, and unprecedented operational difficulties. In addition, in an effort to resume normalcy across the country and the reliance on widespread accessible testing to achieve this, the Department of Health and Human Services ("HHS") has authorized and called on pharmacists across the country to conduct COVID-19 diagnostic and serology testing.³ This has required a diversion of any extra personnel and hours to implement and conduct COVID-

³ HHS, Office of the Assistant Secretary for Health, *Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act* (Issued Apr. 8, 2020).

19 testing. Dispensers must remain focused on providing uninterrupted care to America's patients during this extraordinary time and enforcement discretion for these sections will help pharmacists and pharmacies maintain that focus.

Because dispensers are required to only do business with authorized trading partners⁴ and all of their authorized trading partners are required to only engage in transactions involving a product if it is encoded with a product identifier (except as provided pursuant to subsection (a)(5)),⁵ it is highly likely that product that dispensers receive after November 27, 2020, will be encoded with the product identifier, as applicable. However, because of the concerns listed above, dispensers will be challenged to check every package for the product identifier. We recognize that enforcement discretion for section 582(d)(2) would not relieve dispensers of their responsibility to have systems in place to identify suspect and illegitimate product under section 584(d)(4).

The investigation steps outlined in sections 582(d)(4)(A)(ii)(I)-(II) involve a very manual process. Currently, there are no electronic systems in place to verify the lot numbers or the product identifiers. Dispensers will have to rely on phone, fax, and email correspondence to verify product identifiers. To do this for at least 3 packages or 10 percent of such product, whichever is greater, or all packages if there are fewer than 3, will be very time consuming. In November of this year, we anticipate that dispensers still will be challenged with their COVID-19 front-line healthcare provider responsibilities, COVID-19 testing, potentially COVID-19 immunization, and continued supply chain disruptions. Layering on implementation and conduct of new onset DSCSA responsibilities will cause significant disruption in patient care and can impact product availability.

We are aware that on April 24, 2020, the Healthcare Distribution Alliance ("HDA") requested additional exercise of enforcement discretion for verification of saleable returned drug products. We support their additional extension request because of the importance to maintain availability of drug product in the supply chain while taking the time to implement and validate systems. Consequently, implementation of sections 582(d)(2) and 582(d)(4)(A)(ii)(I)-(II) requires close collaboration with our wholesale distributor trading partners. Extensions of upstream trading partner requirements have direct and indirect impact on downstream partners. Providing the requested dispenser enforcement discretion will ensure that dispensers have adequate time to align their businesses with any changes made upstream.

In conclusion, we request 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. We appreciate FDA's remarkable COVID-19 response efforts. We know that you are immersed in these efforts and would not submit this request unless we believed that it was in the best interest of the supply chain and public health. Thank you in advance for your consideration of our request. If we can provide any additional information, please do not hesitate to contact Kala Shankle at kshankle@nacds.org.

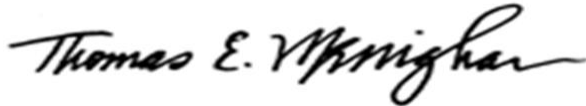
⁴ Section 582(d)(3).

⁵ Sections 582(b)(2) and (c)(2).

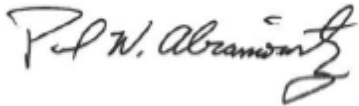
Sincerely,



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