

**Pfizer Inc.**  
275 North Field Drive  
Lake Forest, IL 60045

February 8, 2019

## **Statement on Serialization Requirements Exemption**

While the majority of Pfizer packaging sites and products are compliant with the serialization requirements under DSCSA, certain Pfizer products received an exemption from the FDA from the section 582(b)(2) requirement to affix or imprint a product identifier to each package or homogenous case of product intended to be introduced in a transaction into commerce. This exemption is in effect for certain product packaged from November 27, 2018 to November 26, 2019. Due to this exemption, trading partners (including trading partners who are not Pfizer's immediate customers), including distributors, dispensers, and repackagers, are granted largely parallel relief from DSCSA requirements for these exempted products, with the exception that, while repackagers can accept ownership of exempted product from Pfizer, they must affix product identifiers to the product before selling it. Trading partner exemptions from section 582 include:

- Sections 582(c)(2), (d)(2), and (e)(2)(A)(iii) to only engage in transaction involving product encoded with a product identifier. Specifically, a repackager may accept ownership of such product, but if a repackager wishes to transfer ownership of such product, it must, in accordance with section 582(e)(2)(A)(i), first add a product identifier. This exemption is in effect until expiry of the exempted product packaged without a product identifier by Pfizer from November 27, 2018 to November 26, 2019.
- Sections 582(c)(4)(A)(i)(II), (d)(4)(A)(ii)(II), and (e)(4)(A)(ii)(II) requirements to verify product using the product identifier. However, trading partners must still validate any applicable transaction history and transaction information in their possession and otherwise investigate the product to determine if it is illegitimate in accordance with section 582(c)(4)(A)(i)(II), (d)(4)(A)(ii)(I), (III), and (IV), and (e)(4)(A)(ii)(II). This exemption is in effect until expiry of the exempted product packaged without a product identifier by Pfizer from November 27, 2018 to November 26, 2019.
- Sections 582(c)(4)(D) and (e)(4)(E) requirements to verify the product identifier of saleable returned product packaged without product identifiers by Pfizer before November 27, 2019 that is intended for further distribution. This exemption is in effect until expiry of the exempted product packaged without a product identifier by Pfizer from November 27, 2018 to November 26, 2019.

For questions as to whether a product is affected by this exemption, please contact Pfizer through the [DSCSA@Pfizer.com](mailto:DSCSA@Pfizer.com) mailbox.