

**Meridian Medical Technologies, Inc., a Pfizer company**  
6350 Stevens Forest Road, Suite 301  
Columbia, MD 21046

March 21, 2019

### **Statement on Serialization Requirements Exemption**

A Meridian Medical Technologies, Inc., a Pfizer Inc. company (“MMT”) licensed product has 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 CYANOKIT (NDC 11704-370-01) packaged from November 27, 2018 to May 27, 2019. Due to this exemption, trading partners (including trading partners who are not MMT’s immediate customers), including distributors, dispensers, and repackagers, are granted largely parallel relief from DSCSA requirements for this exempted product, with the exception that, while repackagers can accept ownership of exempted product from MMT, 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 from November 27, 2018 to May 27, 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 sections 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 from November 27, 2018 to May 27, 2019.
- Sections 582(c)(4)(D) and (e)(4)(E) requirements to verify the product identifier of saleable returned product packaged without product identifiers before May 27, 2019 that is intended for further distribution. This exemption is in effect until expiry of the exempted product packaged without a product identifier from November 27, 2018 to May 27, 2019.

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