



March 27<sup>th</sup>, 2019

PuraCap Caribe, LLC  
Road 698 Km 0.8  
Mameyal Ward  
Dorado, PR 00646

### Statement on Serialization Requirements Exemption

PuraCap Caribe, LLC received an exemption from FDA from 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 June 30, 2019. Due to this exemption, trading partners (including trading partners who are not PuraCap Caribe'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 PuraCap Caribe, 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 PuraCap Caribe from November 27, 2018 to June 30, 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 PuraCap Caribe from November 27, 2018 to June 30, 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 PuraCap Caribe 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 PuraCap Caribe from November 27, 2018 to June 30, 2019.

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

  
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Gilberto Lleras-Moreno  
QA Manager

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