

Mobius Therapeutics, LLC™
General Transaction Statement for
Mitosol®

Mobius Therapeutics, LLC™ (the drug manufacturer) certifies that we are transferring ownership of the Mitosol® lot and quantity specified on the Packing List to an authorized trading partner (Foundation Care LLC), as required under DSCSA, and we do not knowingly ship a suspect or illegitimate product, we do not knowingly provide false transaction information, and we do not knowingly alter the transaction history.

As the manufacturer, we initiate the Transaction Information and Transaction History and that information can be found on the Packing List accompanying every shipment. There is no prior transaction history requiring verification on our part.

The general chain of custody for every Mitosol® product shipped is as follows:



FDA has determined that Mitosol® falls under the transaction exemption related to “medical convenience kits” outlined in section 582(24)(B)(xiii); Mobius therefore does not need to comply with the product tracing and product identifier requirements of sections 582(b)(1) and (b)(2), and exemptions from these provisions through the WEER process is unnecessary.

Mobius continues to comply with:

- The section 581(2)(A) requirement to be an authorized trading partner and engage in business only with trading partners that are also authorized in accordance with section 582(b)(3).
- The section 582(b)(4)(A)(i)(I) requirement to quarantine suspect product within the possession or control of Mobius from product intended for distribution until such product is cleared or dispositioned.
- The part of section 582(b)(4)(A)(i)(II) that requires manufacturers to “otherwise investigate the product to determine if it is illegitimate.”
- The section 582(b)(4)(C) requirement to conduct an investigation of a suspect product to determine if it is illegitimate upon a request from an authorized trading partner in possession or control of a product that it believes to be manufactured by Mobius as well as the requirement to notify the trading partner if Mobius has reason to believe that the product is illegitimate.

For further questions please contact Mobius™ Quality Assurance group at 1-877-393-6486 or drugtracing@Mobiustx.com