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), 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:

The Transaction Information, Transaction History and Transaction Statement required by DSCSA all appear on the Packing List accompanying every shipment.

FDA has granted Mobius Therapeutics, LLC™ exemption from the following section 582 requirements for Mitosol® (NDCs 49771-002-01, 49771-002-02, and 49771-002-03) through April 12, 2020:

- 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.
- Section 582(b)(4)(A)(i)(II) requirement to verify product using the product identifier. Mobius will still maintain applicable transaction history and investigate any potential illegitimate product events.
- Section 582(b)(4)(C) requirement that upon request from an authorized trading partner in possession or control of a product that it believes to be manufactured by Mobius™, we (Mobius™) verify the product using the product identifier. All other requirements of 582(b)(4)(C) must still be met.
- Section 582(b)(4)(E) requirement to verify the product identifier of a saleable returned product that is intended for further distribution. As well as section 582(b)(2)(A) to add a product identifier before redistributing such product.

These exemptions extend to all Mobius™ trading partners currently engaged in the sale and distribution of Mitosol®. For further questions please contact Mobius™ Quality Assurance group at 1-877-393-6486 or drugtracing@Mobbiustx.com

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