Drug Supply Chain Security Act (DSCSA) Frequently Asked Questions

Q. Is Anda currently compliant with the track-and-trace requirements of Drug Supply Chain Security Act (DSCSA)?

Yes. Anda, Inc., a Florida company that purchases all prescription products directly from the manufacturers of those products, is fully compliant with all provisions of DSCSA which took effect January 1, 2015. Prior to January 1st, 2015, Anda was fully compliant with Florida pedigree law which has been incorporated into the DSCSA.

All Anda and AndaMEDS invoices contain all the information that is required by DSCSA of a wholesale distributor that purchases prescription products directly from the manufacturers of those products, including the following statement (see Exhibit A):

This wholesale distributor, or a member of its affiliated group, purchased the product directly from the manufacturer, exclusive distributor, or repackager that purchased directly from the manufacturer. This wholesale distributor has complied with each applicable subsection of FDCA sec. 581 (27) (a) - (g).

If you would like a reprint of any invoice, please contact your Sales Representative. All Anda or AndaMEDS customers with an active www.andanet.com or www.andameds.com account can view/print their invoices over the prior two years via the Order History page (see Exhibit B). To register for online access, please visit www.andanet.com or www.andameds.com and click on Register for Online Access or contact your Sales Representative at 1-800-331-ANDA (2632).

Customers who are set up on Anda’s Electronic Data Interchange (EDI) system will be able to access and store all information that is required to be maintained by purchasers of pharmaceutical products. The EDI documentation that provides the required DSCSA information is the 856 Advanced Ship Notice (ASN). Please contact Anda Technical Support at 1-877-263-2638 with any questions.

Q. Does Anda maintain all of the required information for a period of at least six years?

Yes. Anda has always maintained a complete history of each customer invoice for as long as the customer has been ordering from Anda. If you would like a reprint of any invoice, please contact your Anda Sales Representative. If you have an active www.andanet.com or www.andameds.com account, you can view/print invoices over the prior two years via the Order History page (see Exhibit B). To register for online access, please visit www.andanet.com or www.andameds.com and click on Register for Online Access or contact your Sales Representative at 1-800-331-ANDA (2632).

Q. How does a customer access their invoices thru Electronic Data Interchange (EDI)?

Customers that are set up on Anda’s Electronic Data Interchange (EDI) system will be able to access and store all required information via the EDI 856 Advanced Ship Notice (ASN).

- EDI customers that are utilizing TraceLink, a track-and-trace vendor, will automatically be set up through Anda’s IT Department to establish connectivity. Anda is not a TraceLink customer, however an agreement has been established to connect Anda’s EDI TraceLink customers.
- For EDI customers that are utilizing a track-and-trace vendor other than TraceLink, Anda has the ability to implement connectivity with other vendors. Please contact Anda Technical Support at 1-877-263-2638 with any requests.

Q. How does a customer access the required information if they are not on Electronic Data Interchange (EDI)?

If you would like a reprint of any invoice, please contact your Anda Sales Representative. Any customer with an active www.andanet.com or www.andameds.com account can access their invoices over the prior two years via the Order History page (see Exhibit B). To register for online access, please visit www.andanet.com or www.andameds.com and click on Register for Online Access or contact your Anda Sales Representative at 1-800-331-ANDA (2632).

Q. When will FDA take enforcement action against dispensers of prescription drugs that do not capture and maintain the product track-and-trace information as required by DSCSA?

On October 29th, 2015, the FDA announced that it does not intend to take enforcement action until January 1st, 2016 against dispensers of prescription drugs that do not capture and maintain the product tracking and tracing information as required by DSCSA. The previous deadline was November 1st, 2015. If you would like to view the complete FDA document that was published on June 30th, it can be found on the FDA website at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM453225.pdf
July 6, 2015

Dear Valued Customer,

In our continuing effort to provide our customers with updated information regarding significant industry developments, we have included a description of the Drug Supply Chain Security Act (DSCSA) which amends the Federal Food, Drug and Cosmetic Act (the “Act”) that was signed into law in November 2013. The Act took effect January 1, 2015, and provides for a full implementation process over a period of 10 years. As indicated below, the Act imposes requirements on manufacturers, wholesaler drug distributors, repackagers and dispensers to verify that all pharmaceutical products are legitimate, utilizing identification and tracing procedures as well as maintaining systems that recognize and report suspect products.

On October 29th, 2015, the FDA announced that it does not intend to take enforcement action until March 1st, 2016 against dispensers of prescription drugs that do not capture and maintain the product tracking and tracing information as required by DSCSA. The previous deadline was November 1st, 2015. If you would like to view the complete FDA document that was published June 30th, it can be found on the FDA website at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM453225.pdf.

Please be advised that Anda purchases the products that are sold to our customers directly from the manufacturers of those products. Anda is currently providing all of the items required of wholesale distributors by the Act as per the following provisions:

- Section 582(c)(1)(A)(ii)(I)(aa) states: “If the wholesale distributor purchased a product directly from the manufacturer,….the wholesale distributor shall provide to the subsequent purchaser—(AA) a transaction statement, which shall state that such wholesale distributor,….purchased the product directly from the manufacturer……; and (BB) subject to subclause (II), the transaction history and transaction information.

- (II) For purposes of transactions described in subclause (I), transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer.”

- Since Anda purchases such products directly from the manufacturer, the preceding section (II) applies to the transaction statement that Anda is required to provide to its customers.

In summary, the Act requires that a wholesale distributor purchasing a product directly from a manufacturer provide a transaction statement, transaction history, and transaction information to the subsequent purchaser. Such transaction history and transaction information are not required to include the lot number of the product, the initial transaction date or the initial shipment date from the manufacturer.

All Anda and AndaMEDS invoices contain all the information required by the Act, including the following statement that covers all prescription products covered by the DSCSA:

This wholesale distributor, or a member of its affiliated group, purchased the product directly from the manufacturer, exclusive distributor, or repackager that purchased directly from the manufacturer. This wholesale distributor has complied with each applicable subsection of fdca sec. 581 (27)(a)-(g).

Additionally, customers who are set up on Anda’s Electronic Data Interchange (EDI) system will be able to access and store all information that is required to be maintained by purchasers of pharmaceutical products.

If you should have any questions, please contact your Anda Sales Representative at 1-800-331-ANDA (2632). Thank you for your continued business.

Anda Regulatory Compliance Department
**Additional Information**

If you would like more information about the Act including the full text, it can be found on the FDA website at:

- The FDA web page outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S.

Additionally, the Healthcare Distribution Management Association (HDMA) has developed the following resources:

- **Qs and As on the Drug Supply Chain Security Act**: http://image.andanet.com/docs/shared/HDMAQsandAs.pdf
- **Traceability Scenarios**: http://www.healthcaredistribution.org/~/media/pdfs/government-affairs(traceability-resource-2014)“transaction-scenarios.ashx

**Background**

Ten years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. The new system will:

- Enable verification of the legitimacy of the drug product identifier down to the package level
- Enhance detection and notification of illegitimate products in the drug supply chain, and
- Facilitate more efficient recalls of drug products

Drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called upon to work in cooperation with FDA to develop the new system over the next 10 years. Among key provisions that will be implemented over the next 10 years are requirements for:

- **Product identification**: Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- **Product tracing**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- **Product verification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- **Detection and response**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- **Notification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.
- **Wholesaler licensing**: Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.
- **Third-party logistics provider licensing**: Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

The law requires FDA to develop standards, guidance documents, and pilot programs and to conduct public meetings, in addition to other efforts necessary to support efficient and effective implementation. FDA is developing a schedule for implementing the law’s requirements. This system will enhance the FDA’s ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers. Failure to comply with the requirements of the law can result in penalties.

If you should have any questions, please contact your Anda Sales Representative.
### Exhibit A: Invoice Example

**Anda, Inc.**
2915 Weston Road
Weston, FL 33331

1-800-331-2632

#### Schedule 2

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#### Reprint

INVOICE NO. 40001234

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**Sold To:**

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</table>

**Order No.** | **Purchase Order No.** | **Ord. Date** | **DEA No.** | **Exp. Date** | **SLBN** | **Terms** | **Inv. Date** | **Due Date** |
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#### Order

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<tr>
<td>1</td>
<td>70045</td>
<td>2 MORPHINE SULFATE KR 30MG</td>
<td>100</td>
<td>78 MS CONTIN 30MG (MALL)</td>
<td></td>
<td><strong>MALL</strong></td>
<td></td>
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**Med:** MALLINCKRODT LLC 172 RAILROAD AVE BLD 9, KOBART, NY 13788

**NDC# 00406-8310-01** ANP - | | LOT# | EXPIRES: 7/11/17 | *CONTRACTED PRICE*

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**NON ORDER VIA INTERNET**: WWW.ANDANET.COM

**Tracking Numbers:**

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**1, 2, 3, 4, 5** NEXT TO THE ITEM NUMBER DENOTES THAT THE PRODUCT IS A SCHEDULE I, II, III, IV, V DRUG

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THIS WHOLESALE DISTRIBUTOR, OR A MEMBER OF ITS AFFILIATED GROUP, PURCHASED THE PRODUCT DIRECTLY FROM THE MANUFACTURER, EXCLUSIVE DISTRIBUTOR, OR A REPACKAGER THAT PURCHASED DIRECTLY FROM THE MANUFACTURER. THIS WHOLESALE DISTRIBUTOR HAS COMPLIED WITH EACH APPLICABLE SUBSECTION OF FDCA SEC. 581[27][A]-(G).

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PLEASE MAKE CHECKS PAYABLE TO:

**Anda, Inc.**
P.O. Box 930219
Atlanta, GA 31193-0219

**Fulfilled by:** Anda Pharmaceuticals Inc.
6500 Adelaide Ct.
Groveport, OH 43125

**Please Pay This Amount By Due Date:**

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**Page 1 of 1**
Exhibit B: How to Reprint Invoices on andanet.com or andameds.com

Anda and AndaMEDS invoices provide all of the information that is required by DSCSA of a wholesale distributor that purchases prescription products directly from the manufacturers of those products. If you would like a reprint of any invoice, please contact your Sales Representative. Anda or AndaMEDS customers that have an active www.andanet.com or www.andameds.com account can view/print their invoices over the prior six years by following the steps below. To register for online access, please visit www.andanet.com or www.andameds.com and click on Register for Online Access or contact your Sales Representative.

1. To View/Print Invoices, Click “My Account”

2. Click “Order History”

3. Click the desired “Invoice”

4. Click “Download Invoice” or “Print Invoice”

5. To edit order history timeframe: Click “My Account” Go to User Preferences Ex. 730 days = 2yrs. Save Changes
Any customer seeking to obtain an agreement from ANDA regarding maintaining and providing transaction information as referenced in the DSCSA may utilize this document.
DRUG SUPPLY CHAIN SECURITY ACT AGREEMENT

As of JUNE 1, 2015, ANDA, INC. ("ANDA") agrees to confidentially maintain transaction data for all products purchased by Customer from ANDA that is required by the Drug Supply Chain Security Act ("DSCSA"), an amendment to the Federal Food, Drug and Cosmetic Act, for wholesale distributors purchasing products directly from the manufacturers of those products.

ANDA shall maintain the transaction data for six years from the transaction date at no charge to Customer in accordance with the requirements of the DSCSA. The transaction data will be available online via a web portal that Customer can securely access to obtain data for a specific transaction.

Transaction data shall only be available for DSCSA-eligible product sold by ANDA to Customer.

I have read and agree to the terms of this Agreement.

CUSTOMER:

By: _______________________

Name: _____________________

Title: ______________________