

Drug Supply Chain Security Act (DSCSA)

In our continuing effort to provide our customers with updated information regarding significant industry developments, we have included a link below with the FDA's Drug Supply Chain Security Act (DSCSA) Law and Policies which amends the Federal Food, Drug and Cosmetic Act (the "Act") that was signed into law in November 2013.

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 tracking procedures as well as maintaining systems that recognize and report suspect products.

If you would like to view the complete **DSCSA documents**, it can be found on the [FDA website](#).

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.

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 during this 10 year period which started in 2013. Among key provisions that will be implemented over this 10 year period 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.

Frequently Asked Question & Invoices

FAQ

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).

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.

How To Obtain an Invoice

You can easily access your invoices online, by phone or via EDI transmission.

Online: Sign in to your online account and go to Order History. Here you will be able to view/print one year of invoices (**see Exhibit B**). **If you need to obtain a copy of an invoice that is older than one (1) year you can obtain it by contacting a Customer Service representative.**

- **Anda:** www.andanet.com
- **AndaMeds:** www.andameds.com

Phone: Contact a Customer Service Representative for assistance obtaining any invoices you need.

- **Anda:** 1-800-331-2632
- **AndaMeds:** 1-855-772-2879

Electronic Data Interchange (EDI): 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.

- 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 EDI requests.

Additional Information

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.

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."**

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.

If you should have any questions, please contact your Sales Representative. Thank you for being our valued customer.

Anda
1-800-331-2632
Mon - Fri: 9:00 a.m. - 9:00 p.m. ET
Sat: 10:00 a.m. - 3:00 p.m ET

AndaMEDS
1-855-772-2879
Mon - Fri: 9:00 a.m. - 7:00 p.m. ET

Resources

If you would like more information about the Act including the full text, it can be found on the [FDA website](#).

- 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 Alliance (HDA) has developed the following resources:

- [Qs and As on the the Drug Supply Chain Security Act.](#)
- [Traceability Scenarios.](#)

Exhibit A: Invoice Example



SOLD BY:
 ANDA, INC.
 2915 WESTON RD.
 WESTON, FL 33331
 License # 2220244

SOLD TO: [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

REPRINT
 INVOICE
 NO. [REDACTED]
 REPRINT [REDACTED]

SHIPPED BY:
 ANDA PHARMACEUTICALS INC.
 8644 POLK LANE
 OLIVE BRANCH, MS 38654
 License # 15142/16.5
 License # CS15142/16.5
 DEA No. RA0481894

SHIP TO: [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

Order No.	Purchase Order No.	Ord. Date	SLMN	Terms	Inv. Date	Due Date	Carrier	No. of Boxes
[REDACTED]	[REDACTED]	12/16/15	[REDACTED]	[REDACTED]	12/16/15	1/08/16	FEDRX	1

Qty.	Item No.	Description	Size	FM	Compare To	Price	Ext. Amount
1	601628	RANITIDINE HCL SYR 15MG/ML NDC# 54838-0550-80 AMP - [REDACTED] LK	473ML	SY	ZANTAC SYR 15MG/ML (LANN)	[REDACTED]	[REDACTED]

Tracking Numbers: [REDACTED] # LINES: [REDACTED] TOTAL AMP: [REDACTED] TOTAL GOODS: [REDACTED]

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

PLEASE MAKE CHECKS PAYABLE TO:
 ANDA, INC.
 P.O. BOX 930219
 ATLANTA, GA 31193-0219
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WWW.ANDANET.COM
 1-800-798-5078

Cash Discount [REDACTED]
Please Pay This Amount By Due Date → 1/07/16
 After Due Date [REDACTED]



Exhibit B: Reprint Invoices Online

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.

Follow the steps below to access your invoices online.

1. Go to either www.andanet.com or www.andameds.com and sign in to your online account with your username and password.

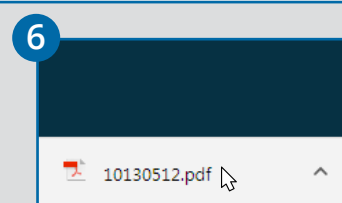
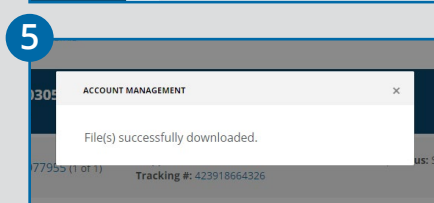
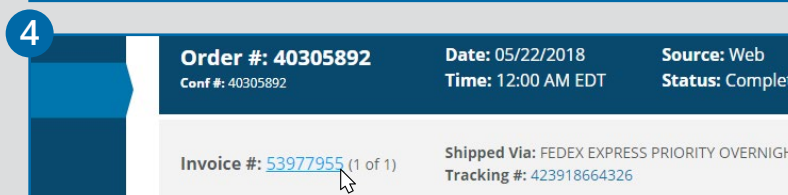
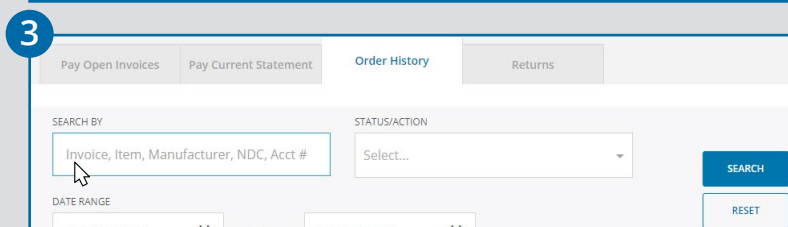
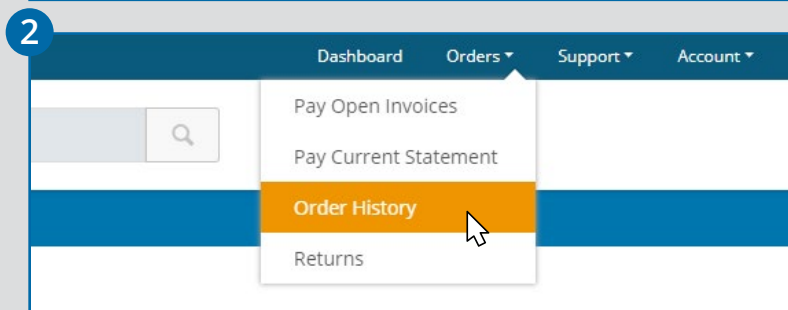
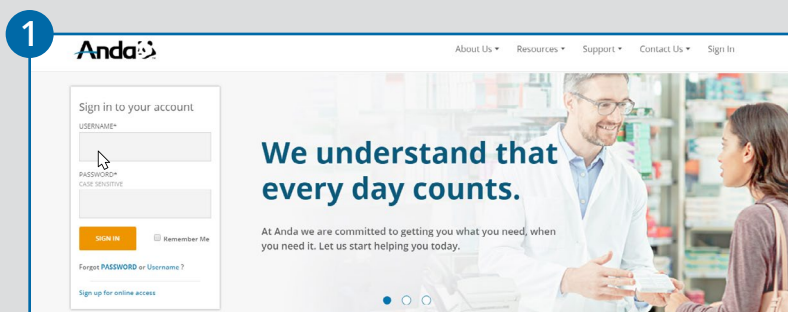
2. When logged in, click **Orders**, then click on the **Order History** tab.

3. In **Order History**, enter the invoice number you are looking for and press **Search**.

4. Click on the invoice number displayed with the order information.

5. Once the invoice number is clicked, you will then get a message stating the **“File(s) successfully downloaded.”**

6. The PDF document is now downloaded to your computer and will be available in the lower left side of your screen for you to open, view, and print.



Note: Anda or AndaMEDS customers with online accounts can view/print one year of invoices. **If you need to obtain a copy of an invoice that is older than one (1) year, you can obtain it by contacting Customer Service.**