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User Manual and Order Guide



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Section 6: Technical Specifications

The software and applications that are used in the signing of electronic CII for the Controlled Substance Ordering System (Andrx CSOS) were certified for compliance in accordance with the Code of Federal Regulations Title 21 Parts 1311.55b and 1311.55c

- The application used to authenticate your electronic signature has been audited and accredited by The Drummond Group. Drummond Group Inc. acting as a neutral, independent 3rd party conducted tests in the following areas;
 - a. Interoperability
 - b. Conformance
- 2. Utilizing FIPS approved cryptographic algorithms

Section 1: Getting Started

A. OVERVIEW

Thank you for choosing the Andrx CSOS software application. With the Andrx CSOS package you will be able to order your CII products electronically, record an electronic record of your order, and record the receipt of the items received from your original order.

During the install, configuration, and test order process you will be guided by one of our Andrx CSOS Support Personnel to ensure that your transition to electronic ordering of your CII product is smooth.

B. DEA RULES AND STANDARDS

The DEA has rules and standards in place for pharmacies willing to participate in the ordering of CII products electronically. This electronic method of ordering cuts down on the use of the current paper Form 222 by replacing it with an e222 form (electronic 222).

				DEA e2	22 Form		
	No order for			ssued for Schedule I and II sub on form has been received. (21 (completed	OMB APPROVAL No. 1117-0010
(Nai	To: ne of Supplier)	GARF	RETT	T'S PHARMACY, INC	Date: (MM-DD-YYYY)	09 - 08 - 200	5
	oplier's DEA Registration Number	AG63	3251	93			
Line No.	No. of Packages	Size o Packag		Name of Item			National Drug Code
1	5	СТ		OXYCODONE/APAP 5/325 MG			00406051201
2	4	СТ		DURAGESIC 75 MCG/HR			50458003505
3	5	СТ		METHADONE HCL 10MG			00054457125
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Signin	n certificate	· cert	1 D	epartment of Justice			
assw			. 0	Approve	Reject		

To ensure proper security measures, the DEA is using the Public Key Infrastructure (PKI) technology.

This technology is put in place for use with a digital certificate. This digital certificate is created with the X.509 standard and defines the pharmacy's name, their public key, and the certificates validity period. This process includes the following advantages:

- 1. Reduce the amount of paper in the process
- 2. Speed transaction times
- 3. Lower costs per transaction
- 4. Introduce security services into the process

Note: You may review the Final Ruling from the DEA by visiting their website www.deaecom.gov

C. PC SYSTEM REQUIREMENTS

The system requirements are in place to ensure proper functionality of the application. The following minimum requirements must be met in order for the software package to install correctly and your transactions to run smoothly.

Hardware

- 1. 800MHz or faster Pentium III-class processor (CPU)
- 2. 512 megabytes of Random Access Memory (RAM)
- 3. 600 MB disc space for Activator software and installation (Hard Drive)
- 4. SVGA monitor (Video Graphic Card)
- 5. CD Drive (for installation)

Operating System

- 1. Windows 2000 Server with service pack 3 or later
- 2. Windows XP with service pack 1 or later
- 3. Windows Server 2003

If you use Windows XP with Service Pack 2, download and install J2SE Java Runtime Environment (JRE) 1.4 or later from Sun Microsystems. You can find this at the following URL http://java.sun.com/j2se/1.4.2/download.html. This is required so the browser based user interface operates properly.

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Section 5: After Receiving your Products

A. OPENING YOUR ANDRX CSOS CII APPLICATION

Andrx CSOS Order Receiving function will give you the ability to verify quantity of items received from the original order. When you receive your product and have your invoice in hand, open the Andrx CSOS CII order application (see page 6)

B. HOW TO ENTER IN RECEIVED ITEMS FROM ORDER

Once you are in the **Receiving Function Screen**, enter your invoice number into the "Please enter Invoice No. received". Then click on "**Search**". Your invoice with the items you ordered appears in the table, and you will see: **NDC**, **Description**, **Ordered** (Total items ordered by the pharmacy), **Shipped** (Total items shipped by Andrx), **Received** (Here, you enter in the physical items received in shipment). Once you have entered in the quantities, there is a **Receiver Signature** field. The receiver must enter in their first and last name/first and last initial. Click on **Save**.

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0	Add Gity/State/Zip rders Dates Date Sent by P 10/11/20 der Received by NDC 60951060270 00406697434 58177031304	dress: DBA N Code: BRAD urchaser 05 / Pharmacy Description ENDOCET 5, METHADOSE MORPHINE S	Date Ship 10/14/ 2325 Mg 5 Mg SULFATE IR 15 M	HARMACY2010 S FL from Andrx 2005	34209	Date Rece 0/20/20 Shipped 0 0	Receive
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0	Add Gity/State/Zip rders Dates Date Sent by P 10/11/20 der Received by NDC 60951060270 00406697434 58177031304	dress: DBA N Gode: BRAD urchaser 05 / Pharmacy Description ENDOCET 5, METHADOSE MORPHINE 3 DURAGESIC PERCOCET 5	Date Ship 10/14/ /325 MG E 5 MG SULFATE IR 15 M 75 MCG/HR 5/325MG	HARMACY2010 S FL from Andrx 2005	34209 Ordered 1 1 1 1 1	Date Rece 0/20/200 Shipped 0 0 0 0	Receive 0 0 0

You will not be able to "Save" or "Print" unless you sign the receipt of the products ordered.

8. The **Message Details** screen is displayed. Click the **View received payload** link.

9. The DEA e222 Form is displayed.

Click the **Print** button to print a hard copy for your records.

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			DEA e2	22 Form			
No ord	ler form may	be issued f	or Schedule I and II substances unless a complet	ted application form has	been received, (21 CFR	OMB APPROVAL No. 1117-	
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	(Nerve of suppl	To: anda Ser)		(NN-00-YYYY)	07-29-2005		
Regis	Supplier's D tration Num	EA BB608	6056				
Une No.	No. of Packages	Size of Packages	Name of Item			National Drug Code	
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1	No. of lines						
BA563	egistration No		Name and Address of Registrant DO NOT SHIP TEST CUSTOMER				
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Section 2: Installation and Configuration

When beginning the installation process, you will be assisted by one of our Andrx CSOS technical support personnel. They will guide you through the installation of the software and installation of your DEA certificates. This process is broken into two parts;

A. INSTALLING YOUR ANDRX CSOS SOFTWARE

- 1. Tier one- Will talk you through installing the CD and it's application
- 2. Configuring the ANDRX CSOS Activator

B. CONFIGURING YOUR ANDRX CSOS SOFTWARE FOR ORDERING

- 1. At this time you will be forwarded to our secondary tier support person.
- 2. You will be given a web address to go to. This web address will direct to a Web Ex conference where the support person will commandeer your computer to finish the configuration process.
- 3. Once completed, you will be asked to re-boot your computer.

Please refer to our Install and Configuration guide found in your Installation CD

Section 3: Placing an Order

After the installation and configuration are completed you are now ready to place an order using the Andrx CSOS CII Application. Our support personnel will guide you through this to ensure that you understand the processes and are comfortable with the electronic ordering of CII products.

A. OPENING YOUR ANDRX CSOS CII APPLICATION

You will first open the application by clicking on the Andrx CSOS icon on your desktop.



B. ENTERING YOUR ACCOUNT NUMBER

Once the application opens you will enter in your account number. This will send a request for your account information and populate the fields that are blank. Once this file is retrieved and the information is populated, click on the Save button. In the middle of the application you will see the Andrx CSOS graphic. Below this graphic click on the Order Now button. This will open up our listing of Brand and Generic CII products.

C. SEARCHING AND CHOOSING CII ITEMS

You have two options for searching and choosing items;

- 1. In the search field you may enter an item number/generic name/brand name of a product.
- 2. You may scroll down from the right hand side and in the **Qty** field you may enter in the number you wish to order for that item.

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 The Approve CSOS Order screen is displayed. Enter the approver Password into the text field. Click the Accept button.

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		86	TEST	P TEST CUSTOMER (123456	
ck "Cha	switch Active nge" button o	Customer n the right	Change FT LAUDERDA	ALE, FL 33331	
5 Activ	ator				
∫ ×	csos ൮	🚸 لق	回影画 L Help	Cyclone Activ	ator
	ve CSO		everything is satisfactory, enter your login	n password below and click the approve b	outton.
No on	ler form may	be issued f	for Schedule I and II substances unless a comp CFR 1305.04)	pleted application form has been received. (21	OHB APPROVAL No. 1117- 0010
	T (None of supplie	o: anda e/		Date: 07-29-2005 (MM-00-11111)	
Regis	Supplier's DE tration Numb	A BB608	6056		
Line No.	No. of Packages	Size of Packages	Name of Item		National Drug Code
1	5	EA	DURAGESIC 50 MCG/HR	50458	003405
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 The CSOS Order approval screen is displayed. The Approval status should read, Order approval successful.

You can click a message row to drill down and view the message details.

SOS order approval			
pproval request date From	To	Approval status	
J 29, 2005 3:17:15 PM ANDA1	CSOSDirectorTST	Order approval successful.	
View pending orders			
View past orders			
Configure order sources			
Contribute order sources			

4. The **CSOS** Activator screen is displayed.

Enter the Administrator User ID and Password and click the Login button.

Controlled Substance Ordering System		X
Main Actions Backup Audit Help 의 중 및 장 강 묘 영 상 Active		
	Customer: DO NOT SHIP TEST CUSTOMER (123456) TEST	
click "Change" button on the right	hange FT LAUDERDALE, FL 33331	
CSOS Activator		
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	Licensed to: Andra	
Provide State	p-up blocking software for your browser may interfere with this	
	product. You may want to disable or uninstall such software.	
1		<u>×</u>

5. The **Choose an Order to Approve** screen is displayed Click the **Approval request date** link for the desired order.

	ele mi 🖌 Help	Cyclone Activator	Logout
J K csos 🖻 🌙 🗘 🖻 🕇		Cyclone Activator	Logoue
hoose an order to ap	prove		
pproval request date From	To	DEA registration number	
1 29. 2005 3:17:15 PM ANDA1	CSOSDirectorTST	BA5634452	

D. ACCEPTING ID NUMBER

Once you have completed your search and have finished ordering click on the continue button. This will show you the order that you are about to place. This screen will also show you a computer generated order id number. Click on the Accept button. This will trigger the Andrx CSOS Activator, which is where you will authenticate the order.

E. AUTHORIZING AND SUBMITTING YOUR ORDER

After you have clicked on the Accept button on the Andrx CSOS ordering application, you will see an Activator login screen. The Activator is the actual transaction conduit between yourself and ANDRX.

The following takes place to ensure that you and we are compliant with DEA standards.

- 1. The transaction Activator will take the order after it has been authorized with your password and encrypt it
- 2. It will send this encrypted packet to our Transaction Director.
- 3. Our Transaction Director will authenticate the packet verifying the electronic signature sent by you.
- 4. Once authenticated the director will submit a response to your Andrx CSOS Activator by sending you a message. This can be seen in your Message Details section of the Activator.
- 5. You can look at the details of the transaction and also from this vantage point be able to see the actual e222 form and print out if you want.

You may refer to your Andrx CSOS Order Guide, which is found in your installation CD

Section 4: Andrx CSOS Order Guide

PREREQUISITES

You must complete the steps described in the AndrxCSOS InstallGuide.doc and AndrxCSOSConfigGuide.doc prior to placing orders with your Andrx CSOS software.

1. Start the Andrx CSOS application. The **Controlled Substance Ordering System** window is displayed.

Click the Order Now button to begin the order process.



2. The Order CIIs data grid is displayed.

You can use the Search text field to query for a specific item.

To purchase an item, edit the **Qty** field in the data grid for the corresponding item. Repeat this step for all the items you wish to order.

Click the **Continue** button.

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Acti	ons Back.	up Audit Help					
0		장 🔜 🚳 🔗 🛛 Active	Customer: DO NOT SHIP TE				
_	To due	itch Active Customer	TEST				
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rde	r CII's	-					
		You are creating	his order for Account Numb	er 123456: DO NOT SHIP TEST CUSTO	MER		
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Cont	vol 2 nm	aduct list			_	_	
and III		Brand Name	Generic Name	Manufacturer	Size	Price	Qty +
	700060	DURAGESIC 50MCG/HR	DURAGESIC 50 MC	G/HR JANSSEN	5	117.26	0
		DURAGESIC 75MCG/HR	DURAGESIC 75 MC		5	178.87	0
	200064	DURAGESIC 100MCG/HR	DURAGESIC 100 M	CG/HR JANSSEN	5	237.39	0
		DURAGESIC 25MCG/HR	DURAGESIC 25 MC		5	64.15	0
		RITALIN 5MG	RITALIN 5MG	NOVARTIS	100	48,40	0
	750002	RITALIN 10MG	RITALIN 10MG	NOVARTIS	100	68,99	0
	750003	RITALIN 20MG	RITALIN 20MG	NOVARTIS	100	99.20	0
	750009	ORAMORPH SR 30MG	ORAMORPH SR 30M	G AAI PHARMACEU	TI 100	117.00	0 -
	750010	ORAMORPH SR 100MG	ORAMORPH SR 100	MG AAI PHARMACEU	TI 25	153.69	0
	750012	ORAMORPH SR 60MG	ORAMORPH SR 60M	G AAI PHARMACEU	TI 100	228.29	0
	750013	TYLOX 5-500MG	TYLOX 5-500MG	J O M PHARM	100	107.82	0
	750015	RITALIN-SR 20MG	RITALIN-SR 20MG	NOVARTIS	100	150.16	0
	750037	ORAMORPH SR 60MG	ORAMORPH SR 60M	G AAI PHARMACEU	TI 25	97.71	0
	750039	ORAMORPH SR 15MG	ORAMORPH SR 15M	G AAI PHARMACEU	TI 100	61.56	0
	750040	ORAMORPH SR 15MG 4X25RN	ORAMORPH SR 15M	G 4X25RN AAI PHARMACEU	TI 100	97.89	0
	750043	OXYCONTIN 10MG SR	OXYCONTIN 10MG	SR PURDUE	100	130.48	0
	750044	OXYCONTIN 20MG CR	OXYCONTIN 20MG	CR PURDUE	100	249.67	0
	750045	OXYCONTIN 40MG CR	OXYCONTIN 40MG	CR. PURDUE	100	443.01	0
	750046	OXYIR 5 MG	OXYIR 5 MG	PURDUE	100	31.46	0
	750055	OXYCONTIN BOMG CR	OXYCONTIN 80MG	CR PURDUE	25	226.46	0
	750058	DEMEROL 100MG/ML	DEMEROL 100MG/M	L HOSPIRA	25X1M	12.98	0
	750060	DEMEROL 50MG/ML 25X2ML	DEMEROL 50MG/ML	25X2ML HOSPIRA	25X2M	11.18	0
	750062	DEMEROL 50MG/ML 25X1ML	DEMEROL 50MG/ML	25X1ML HOSPIRA	25×1M	8.40	0
	750063	DEMEROL 100MG/ML	DEMEROL 100MG/M	L HOSPIRA	20ML	22.42	0
	750064	DEMEROL 50MG/ML 30ML	DEMEROL 50MG/ML	30ML HOSPIRA	1	17.12	0
		KADIAN SR 20MG	KADIAN SR 20MG	AI PHARMA	60	131,49	0

3. The **Order Confirmation Screen** is displayed. Verify the items selected and quantity desired.

If there is a problem with any item, click the **Continue Shopping** button and return to the previous step. If the order details are correct, click the **Confirm Order** button.

If you wish to print this order, click the **Print** button.

			Active Customer: DO NOT SHIP TEST CUSTOME TEST		
	To switch Active (ck "Change" button on		Change FT LAUDERDALE, FL 33331		
rde	er Confirmation Sc	reen			
	Review the foll	owing	list of CII items entered. You could change the CSOS accepting the order.	Unique Identification numbe	r at any time before
Nex	ct CSOS Unique Id	entific	ation Number: 000001		
	No. Quantity Si	ze	Generic Name	Price	NDC
۶.	1 5 5		DURAGESIC 50 MCG/HR	100.50	50458003405
	2 3 10	10	ORAMORPH SR 30MG	103.55	00054480525