

Pedigree Processing Overview



The Systems House, Inc.

TSH User Group Meeting

Monday, June 23rd 2008, Clifton, New Jersey



What is a Pedigree?

- ❑ The Prescription Drug Marketing Act of 1987 (PDMA) was signed into law by the President April 12, 1988.
- ❑ The PDMA was enacted to ensure that drug products purchased by consumers are safe and effective
- ❑ To avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs.
- ❑ The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs.

States Requiring Pedigrees



A majority of states have or are considering pedigree legislation.

- 21 states have pedigree laws or rules today
- An additional 14 states have proposed legislation or rules
- The PDMA pedigree rules set the minimum bar

Pedigree MDS Overview

- ❑ The MDS Pedigree System is a hybrid that will allow adoption of the Electronic pedigrees as the Industry creates a standard.
- ❑ Currently it allows both scanning and manual input of pedigree and authentication information.
- ❑ From the point of receipt into the warehouse to the point of shipment each item is tracked thru the warehouse and is associated with an internal pedigree code.
- ❑ This code is then provided with each shipment and can provide a generic Pedigree form electronically or on paper. Alternately the Pedigree can be made available via a distributor's website.

Maintenance for Pedigrees

- ❑ Product maintenance must be a lot item, serial number is optional
- ❑ Drug type maintenance sets Pedigree flag
- ❑ Vendor maintenance able to sell drugs and set up to track Pedigree
- ❑ Customer maintenance must be set up to purchase drugs

Pedigree Processing

□ Receiving

- Purchase Order and Non Po Receipts
- Manually Update Additional Inbound Information
- Scan in Backup Documents

□ Shipping

- Outbound Updated with Shipping Info
- Print / Email / Fax a Pedigree

Purchase Order Receiving

- ❑ At this point the MDS system creates a pedigree (sequential number) with information about the product and qty with lot details, whom it was purchased from, how much and any serial numbers or expiration dates.
- ❑ You can then manually update any additional information into the MDS system and scan backup documents such as the paper pedigree you have received – if an electronic format becomes available you would use the same process to import the electronic pedigree.

Pedigree Menu

Account:41 BASE 12 Port:041 Menu:PEDIGREE.MENU Capture:On

1. Pedigree Update

2. Print Pedigree Form

Enter Selection or END :

CONTACTS	MAINT	DRILL	EXECING	REPORTS	CAPT OFF	VIEW	CRM.MENU	VRM.MENU		
HELP	OKEND	INSEH	LDELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	OFF		F000P

Pedigree Update

- You can search by a number of criteria to find the pedigree the system created

Pedigree Update

Pedigree Update

Pedigree ID

1. PO#

2. Product#

3. Company

4. Notes

5. Shipment ID

6. Invoice#

7. Invoice Date

8. Manufacturer

9. NDC#

10. Dosage Form

11. Strength

12. Container Size

13. Lot#

Lot Qty

Add Inbd	Add Outbd			Scroll Dn	Scroll Up						
HELP	OK/END	INSERT	LDELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	Off			Popup

Pedigree Update

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HELP	OK/END	INSERT	LDELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	Off			Popup

Pedigree Update

Pedigree Update

Pedigree ID

1. PO#

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7. Invoice Date

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Lot Qty

Add Inbd	Add Outbd			Scroll Dn	Scroll Up						
HELP	OK/END	INSERT	LDELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	Off			Popup

Pedigree Update

Pedigree Update

Pedigree ID	0000000112	
1. PO#	011320100	
2. Product#	ADVIL	ADVIL
3. Company	01 The Systems House, Inc	
4. Notes		
5. Shipment ID	1234	
6. Invoice#	V6665	
7. Invoice Date	09/03/07	
8. Manufacturer	ADVIL MNF	
9. NDC#		
10. Dosage Form	1 TAB	
11. Strength	00 MG	
12. Container Size	BOTTLE	
13. Lot#	Lot Qty	
100407A	1250	
100407B	1250	

ENTER LINE # TO CHANGE, DELETE TO DELETE, 0 TO ACCEPT : XXXXXX PAGE 1 OF 3

Add Inhd	Add Outbd		Scroll Dn	Scroll Up						
HELP	OK/FND	INSERT	DEL/ETE	PREV PG	NEXT PG	INQUIRY	CANCEL	OFF		Print

Pedigree Inbound Update

- ❑ The inbound page allows you to update the inbound shipping information
- ❑ Note: many pedigrees have multiple inbound vendors in the supply chain and MDS allows entry of all of them.
- ❑ To save time on entry you can search thru existing vendors and mfg's in your vendor master table to add to the pedigree

Pedigree Inbound Update

PEDIGREE Update

Pedigree ID:

14. Inbound Sold To/Ship To
Line: Total:

	Sold to	Ship to
Wholesaler ID	<input type="text" value="A1200"/>	<input type="text" value="A1200"/>
Name	<input type="text" value="The Systems House, Inc."/>	<input type="text" value="The Systems House, Inc."/>
Address 1	<input type="text" value="1033 Route 46 F."/>	<input type="text" value="1033 Route 46 F."/>
Address 2	<input type="text"/>	<input type="text"/>
City	<input type="text" value="CLIFTON"/>	<input type="text" value="CLIFTON"/>
State	<input type="text" value="NJ"/> Country: <input type="text" value="000"/> U.S.A.	<input type="text" value="NJ"/> Country: <input type="text" value="000"/> U.S.A.
/ip	<input type="text" value="07073"/>	<input type="text" value="07073"/>
Date Purchased	<input type="text" value="10/04/07"/>	<input type="text" value="10/04/07"/>
Wholesaler Inv#	<input type="text" value="6605"/>	<input type="text"/>
Recipient	<input type="text" value="JOHN"/>	<input type="text"/>
Authenticator	<input type="text"/>	<input type="text"/>
Email	<input type="text"/>	<input type="text"/>
Phone	<input type="text"/>	<input type="text"/>

ENTER LINE # TO CHANGE,DELETE TO DELETE,0 TO ACCEPT : PAGE 2 OF 3

Add Inbd	Add Outbd		Scroll Dn	Scroll Up						
HELP	OK/END	INSERT	LDELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	OFF		Popup

Pedigree Outbound Update

- ❑ The outbound page will show who you have shipped the pedigree to
- ❑ This information will be filled in automatically by shipping but can also be entered manually
- ❑ To save time on entry you can enter a release number and all of the data will be filled in

Pedigree Outbound Update

PEDIGREE Update

Pedigree ID:

15.Outbound Sold To/Ship To

Line: Serial:

Release#

	Sold To		Ship To	
Wholesaler ID	<input type="text" value="100771"/>		<input type="text" value="M"/>	
Name	<input type="text" value="JULIANNE RAUCO"/>		<input type="text" value="JULIANNE RAUCO"/>	
Address 1	<input type="text" value="1033 RT 46"/>		<input type="text" value="1033 RT 46"/>	
Address 2	<input type="text"/>		<input type="text"/>	
City	<input type="text" value="CLIFTON"/>		<input type="text" value="CLIFTON"/>	
State	<input type="text" value="NJ"/>	Country <input type="text" value="000"/> <input type="text" value="U.S.A."/>	<input type="text" value="NJ"/>	Country <input type="text" value="000"/> <input type="text" value="U.S.A."/>
Zip	<input type="text" value="7013"/>		<input type="text" value="07013"/>	
Date Purchased	<input type="text" value="03/14/07"/>		<input type="text" value="10/04/07"/>	
Wholesaler Inv#	<input type="text"/>		<input type="text"/>	
Recipient	<input type="text"/>		<input type="text"/>	
Authenticator	<input type="text"/>		<input type="text"/>	
Email	<input type="text" value="JULI@TSIINC.COM"/>		<input type="text"/>	
Phone	<input type="text" value="973-777-8050"/>		<input type="text"/>	

ENTER LINE # TO CHANGE,DELETE TO DELETE,0 TO ACCEPT : PAGE 3 OF 3

Add Inbd	Add Outbd		Scroll Dn	Scroll Up						
HELP	OK/END	INSERT	LDELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	OFF		Popup

Pedigree Print Form

- ❑ Pedigrees can be set up to print automatically with the invoice
- ❑ They can be printed from the pedigree menu
- ❑ They can be printed from the invoice inquiry print
- ❑ They can be viewed and printed from the Remotenet website

Print Pedigree Form

Print Pedigree Form

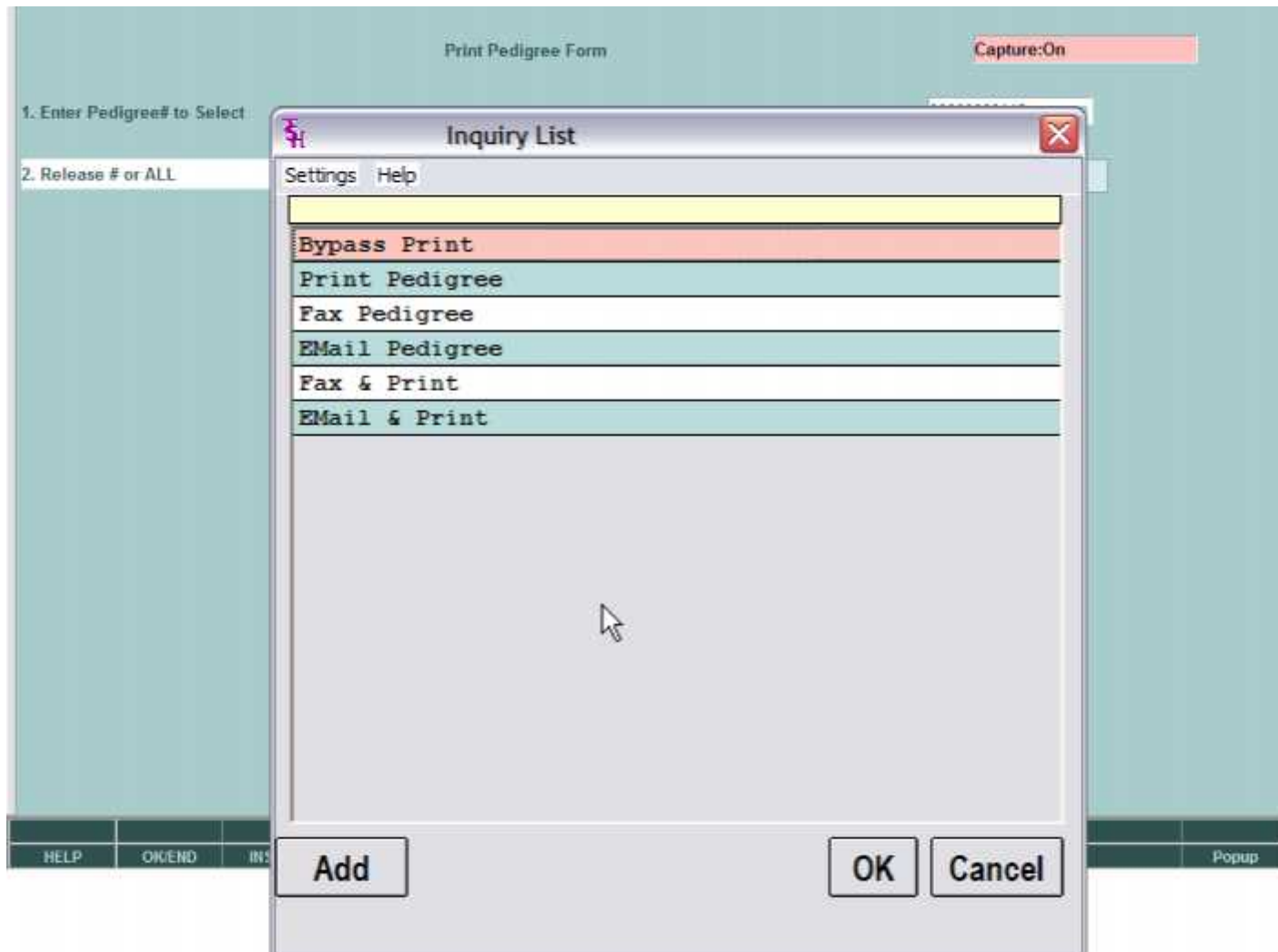
Capture:On

1. Enter Pedigree to Select: 0000000112

2. Release # or ALL: All

HELP	OK/END	INSERT	LDELETE	PREV PG	NEXT PG	CAPT OFF	INQUIRY	CANCEL	OFF			Popup
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Print Pedigree Form



Invoice Reprint Inquiry

Invoice Reprint/Inquiry by Customer

Company# 00

Customer#

Range: of Invoice# Release#

Starting 01143937001

Ending 01143937001

Line	Tax	Invoice#	Release#	Inv Date	Customer	P/O Number	Invoice Amt
1	INV	01503923	01143937001	05/09/08	VERBAL PO		33.20
2							
3							
4							
5							
6							
7							
8							
9							
10							

Enter Tax (INV,IV,C/M,C/V) Invoice# or Release# to re-print:

Select	Un Select	Group On	Group Off	All on	All off	PRINT	Printree			
HELP	OK/END	INSERT	LDELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	OFF		Popup

Invoice Reprint Inquiry

Invoice Reprint/Inquiry by Customer

Company# 00

Customer#

Range: of Invoice# Release#

Starting

Ending

01143937001

01143937001

Line	Tax	Invoice#	Release#	Inv Date	Customer	P/O Number	Invoice Amt
1	INV	01503923	01143937001	05/09/08	VERBAL PO		33.20
2							
3							
4							
5							
6							
7							
8							
9							
10							

Enter Tax (INV,IV,C/M,C/V) Invoice# or Release# to re-print

XXXXXXXXXXXX

Select	Un Select	Group On	Group Off	All on	All off	PRINT	Pedigree				
HELP	OK/END	INSERT	LDELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	MF			Popup

Pedigree Print

The Systems House, Inc. (Wholesaler's Name)
PRESCRIPTION (LEGEND) DRUG PEDIGREE 0500200124
 History of Drug Sales and Distributions

Legend Drug Name, Strength, Dosage Form, Container Size: _____
 This is a repackaged drug (requires repackager's pedigree information and authentication of repackager's pedigree)
 NDC: 1111-2222-333

Lot Number	Quantity	Unique Serial #
101003A	500	
101003B	500	

Reference# Number: 602923
 Document Type: Invoice
 Reference# Date: 05/09/08
(Included in the sale by the wholesaler (downward arrow))

OWNERSHIP HISTORY **PHYSICAL DISTRIBUTION HISTORY**
(if different from the owner information)

Manufacturer's Name: MANUFACTURER
 Manufacturer's information for authentication: _____
1. Wholesaler that purchased from the MANUFACTURER or a REPACKAGER (which requires authentication)

Name: UNIVERSITY MEDICAL CENTER Address: 1 STATION PLAZA THE CITY CENTER OF EDMONT WA 07000 Date Purchased & Ref#: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ <i>To authenticate a subsequent transaction, contact:</i> Name: _____ Telephone number: _____ Email Address: _____	Name: UNIVERSITY MEDICAL CENTER Address: 1 STATION PLAZA THE CITY CENTER OF EDMONT WA 07000 Date Received & Ref#: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ <i>To authenticate a subsequent transaction, contact:</i> Name: _____ Telephone number: _____ Email Address: _____
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2. #1 Above SOLD TO: Name: The Systems House, Inc. Address: 1033 Route 46 L. CLIFTON NJ 07073 Date Purchased & Ref#: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ <i>To authenticate a subsequent transaction, contact:</i>	SHIPPED TO: Name: The Systems House, Inc. Address: 1033 Route 46 L. CLIFTON NJ 07073 Date Received & Ref#: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ <i>To authenticate a subsequent transaction, contact:</i>
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Inventory Transaction by Product

Inventory Transaction History by Product									
Product#		ADVIL				ADVIL			
Warehouse or Alt		ALL	FOM 01	4055	CHR 01	4225			
Ln#	Customer/Vendor Number Customer/Vendor Name	Date Drop Ship	Trx Whts	Release/Ref P/O#/ReasCd	Qty Sell	St	Price Cost	Um GP%	
1	IIMC UNIVERSITY MEDICAL CENTER	06/02/08 ND	INV 001	01144173001	.5	EA	2.00 1.00	GA 50	
2	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	10	EA	1.00	EA	
3	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	-10	EA	1.00	GA	
4	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	10	EA	1.00	EA	
5	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	-10	EA	1.00	EA	
6	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	10	EA	1.00	EA	
7	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	-10	EA	1.00	EA	

Enter line to display:

Detail	OK/END	INSEH	DELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	UP	DOWN
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Inventory Transaction by Product

Inventory Transaction History by Product									
Product#		ADVIL				ADVIL			
Warehouse or Alt		ALL	COM ON	4055	CHR ON	4225			
Ln#	Customer/Vendor Number Customer/Vendor Name	Date Drop Ship	Trx Whts	Release/Ref P/O#/ReasCd	Qty Sell	St	Price Cost	Um GP%	
1	IIMC UNIVERSITY MEDICAL CENTER	06/02/08 ND	INV 001	01144173001	.5 EA	EA	2.00 1.00	GA 50	
2	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	10 EA	EA	1.00		
3	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	-10 EA	EA	1.00		
4	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	10 EA	EA	1.00		
5	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	-10 EA	EA	1.00		
6	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	10 EA	EA	1.00		
7	A1200 C & R REAL ESTATE	06/02/08	RPA 001	005532 132350	-10 EA	EA	1.00		

Enter line to display:

Detail	OKMENU	INSERT	DELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	UP	DOWN
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Inventory Transaction by Product

Inventory Transaction History by Product

Product# ADVIL ADVIL

Warehouse or Alt ALL COM ON 4055 CHR ON 4225

Ln#	Customer/Vendor Number	Date	Tnx	Release/Raf	Qty	Price	Um
-----	------------------------	------	-----	-------------	-----	-------	----

Product Number ADVIL ADVIL

Warehouse 001 WAREHOUSE

Date 06/02/08 TNX INV Quantity -5

Serial Number	Lot Number	Location	Pedigree	Quantity	
1	None	060208A	A-001	00000000197	1
2	None	060208A	A-001	00000000197	1
3	None	060208A	A-001	00000000197	1
4	None	060208A	A-001	00000000197	1
5	None	060208	A-001	00000000197	1
6					
7					
8					
9					
10					

Press END to Continue: XXXXXX



Serial Transaction Inquiry

Lot/Serial Number Transaction Inquiry

Product# Lot Number or ALL
 Serial Number or ALL
 Pedigree ID or ALL
 Warehouse or ALL

Ln#	Lot No.	Whs Lot	Quantity	Tax	Release#	Price	Cust/Vend No.	DS
Serial No.		Pedigree	Date	Whs	P/O#/Ref#	Cost	Cust/Vend Name	
1	060208	A-001	-1	INV	144173001	2.00	UMC	
		00000000197	06/02/08	001	01	1.00	UNIVERSITY MEDICAL CENTE	
2	060208A	A-001	-1	INV	144173001	2.00	UMC	
		00000000197	06/02/08	001	01	1.00	UNIVERSITY MEDICAL CENTE	
3	060208A	A-001	-1	INV	144173001	2.00	UMC	
		00000000197	06/02/08	001	01	1.00	UNIVERSITY MEDICAL CENTE	
4	060208A	A-001	-1	INV	144173001	2.00	UMC	
		00000000197	06/02/08	001	01	1.00	UNIVERSITY MEDICAL CENTE	
5	060208A	A-001	-1	INV	144173001	2.00	UMC	
		00000000197	06/02/08	001	01	1.00	UNIVERSITY MEDICAL CENTE	
6	060208	A-001	-1	RPA			A1200	ND
101			06/02/08	001	132350	1.00	C & R REAL ESTATE	
7	060208	A-001	-1	RPA			A1200	ND
101			06/02/08	001	132350	1.00	C & R REAL ESTATE	

Enter 'END' to EXIT, 'NEXT PG' or 'PREV PG'

HELP	OK/END	INSERT	DELETE	PREV PG	NEXT PG	INQUIRY	CANCEL	OFF			F1000P
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Remote Net / Detail Release Inquiry

Customer #		Sold To				Ship To						
100139		Coastal Birth Control Center Edwardo I. M. Aquino, MD (FRS13) 1901 Morgan AVE				Coastal Birth Control Center 1901 Morgan AVE						
Salesrep		CORPUS CHRISTI, TX 78404				CORPUS CHRISTI, TX 78404						
Salesman GS		U.S.A.										
Web Order#		Order Date	Req. Date	Req. No.	Cust PO	Ordered By	Terms					
		03/06/08	03/06/08		VERBAL		10 EOM					
Order#		Invoice#	Invoice Date		Ship Date	Ship Method						
01002375-001		019432	03/06/08		03/06/08	UPS - Ground						
Special Instructions:												
Release detail for your order:												
Line No.	Product No.	Product Description	Ord Qty	Ord UM	Ship Qty	DkOrd Qty	InPick Qty	Price	Prc UM	Prc Qty	Ext. Price	Est D/O Ship Date
1	00143-2112-05	Doxycycline Hyclate 100mg TB 500 WEST	3	EA	3	0		\$27.50	EA	1	\$82.50	
2	63746-0137-05	Ibuprofen 800mg TB 500 IN TE	2	EA	2	0		\$21.07	EA	1	\$42.14	
TOTALS												
											Freight:	\$0.00
Note: To view your pedigree please click on the pedigree number below.												
Pedigree Information:												
Pedigree #						Ship Date						
00000003309						03/06/08						
00000001103						03/06/08						

Remote Net / Detail Release Inquiry

Customer #		Sold To				Ship To						
100130		Coastal Birth Control Center Edwardo I. M. Aquino, MD (FRS13) 1901 Morgan AVE				Coastal Birth Control Center 1901 Morgan AVE						
Salesrep		CORPUS CHRISTI, TX 78404				CORPUS CHRISTI, TX 78404						
Salesman GS		U.S.A.										
Web Order#		Order Date	Req. Date	Req. No.	Cust PO	Ordered By	Terms					
		03/06/08	03/06/08		VERBAL		10 EOM					
Order#		Invoice#	Invoice Date		Ship Date	Ship Method						
01002375-001		019432	03/06/08		03/06/08	UPS - Ground						
Special Instructions:												
Release detail for your order:												
Line No.	Product No.	Product Description	Ord Qty	Ord UM	Ship Qty	DkOrd Qty	InPick Qty	Price	Prc UM	Prc Qty	Ext. Price	Est D/O Ship Date
1	00143-2112-05	Doxycycline Hyclate 100mg TB 500 WEST	3	EA	3	0		\$27.50	EA	1	\$82.50	
2	63746-0137-05	Ibuprofen 800mg TB 500 IN TE	2	EA	2	0		\$21.07	EA	1	\$42.14	
TOTALS											Freight:	\$0.00
Note: To view your pedigree please click on the pedigree number below.												
Pedigree Information:												
Pedigree #											Ship Date	
00000003309											03/06/08	
00000001103											03/06/08	

Remote Net / Detail Release Inquiry

Customer # 100139	Sold To Coastal Birth Control Center Edwardo L M Aquino, MD (E9513) 1901 Morgan AVE	Ship To Coastal Birth Control Center 1901 Morgan AVE															
Salesrep Salesman GS																	
Web Order#																	
Order# 01002375-001																	
Special Instructions:																	
<p align="center"><small>(Wholesaler's Name)</small> PRESCRIPTION (LEGEND) DRUG PEDIGREE 0000000309 History of Drug Sales and Distributions</p> <p>Legend Drug Name, Strength, Dosage Form, Container Size: <u>Doxycycline Hyclate 100mg</u></p> <p><input type="checkbox"/> This is a repackaged drug (requires repackager's pedigree information and authentication of repackager's pedigree)</p> <p>NDC: 00143-2112-05</p> <table border="1"> <thead> <tr> <th>Lot Number</th> <th>Quantity</th> <th>Unique Sera #</th> </tr> </thead> <tbody> <tr> <td>CLOT0310</td> <td>11</td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>			Lot Number	Quantity	Unique Sera #	CLOT0310	11										
Lot Number	Quantity	Unique Sera #															
CLOT0310	11																
<p align="center">OWNERSHIP HISTORY</p> <p>Manufacturer's Name: _____ Manufacturer's information for authentication: _____</p> <p>1. Wholesaler that purchased from the MANUFACTURER or a REPACKAGER (which requires authentication)</p> <table border="1"> <tr> <td> Name: Coastal Birth Control Center Address: Edwardo L M Aquino, MD (E9513) CORPUS CHRISTI TX 78404 Date Purchased & Ref: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ To authenticate a subsequent transaction, contact: Name: _____ Telephone number: _____ Email Address: _____ </td> <td> Name: Coastal Birth Control Center Address: 1901 Morgan AVE CORPUS CHRISTI TX 78404 Date Received & Ref: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ To authenticate a subsequent transaction, contact: Name: _____ Telephone number: _____ Email Address: _____ </td> </tr> </table>		Name: Coastal Birth Control Center Address: Edwardo L M Aquino, MD (E9513) CORPUS CHRISTI TX 78404 Date Purchased & Ref: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ To authenticate a subsequent transaction, contact: Name: _____ Telephone number: _____ Email Address: _____	Name: Coastal Birth Control Center Address: 1901 Morgan AVE CORPUS CHRISTI TX 78404 Date Received & Ref: _____ Print Name of Recipient: _____ Signature of Recipient: _____ Name of Authenticator: _____ Signature of Authenticator: _____ To authenticate a subsequent transaction, contact: Name: _____ Telephone number: _____ Email Address: _____	<p align="center">PHYSICAL DISTRIBUTION HISTORY <i>(if different from the owner information)</i></p>													
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Pedigree Benefits

- ❑ Hybrid meeting Government Requirements
- ❑ Ability to scan in backup documents
- ❑ Tracked from receipt to shipment
- ❑ Print / Fax / Email of documents
- ❑ Extensive Inquiry Capability