

(Repackager's name)

PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions for a Repackaged Prescription Drug

Description of drug being distributed:

Legend Drug Name, Strength, Dosage Form, Container Size: _____

Manufacturer/Repackager name on container: _____

NDC on container (optional): _____

Lot Number	Quantity	Unique Serial #

Reference* Number: _____
Document Type: _____
Reference* Date: _____
(related to the sale by the repackager identified above)

History of drugs included in the repackaged lot identified above: (include pedigrees for additional drugs on attached pages as necessary)

Lot Number: _____
Quantity: _____
Manufacturer & information for authentication: _____

NDC: _____
Unique Serial#: _____

Repeat as applicable
Lot Number: _____
Quantity: _____
Manufacturer & information for authentication: _____

NDC: _____
Unique Serial#: _____

OWNERSHIP HISTORY	PHYSICAL DISTRIBUTION HISTORY (if different)
1. WHOLESALER/REPACKAGER THAT PURCHASED FROM THE MANUFACTURER	
Name: _____ Address: _____ _____ Date Purchased & Ref * # _____ Print Name of Recipient: _____ Signature of Recipient: _____ To authenticate a subsequent transaction, contact: Name: _____ Telephone Number: _____ Email address: _____	Name: _____ Address: _____ _____ Date Purchased & Ref * # _____ Print Name of Recipient: _____ Signature of Recipient: _____ To authenticate a subsequent transaction, contact: Name: _____ Telephone Number: _____ Email address: _____
SUBSEQUENT WHOLESALE DISTRIBUTIONS (repeat as necessary):	
2. #1 Above SOLD TO: Name: _____ Address: _____ _____ Date Purchased & Ref * # _____ Print Name of Recipient: _____ Signature of Recipient: _____ To authenticate a subsequent transaction, contact: Name: _____ Telephone Number: _____ Email address: _____	SHIPPED TO: Name: _____ Address: _____ _____ Date Purchased & Ref * # _____ Print Name of Recipient: _____ Signature of Recipient: _____ To authenticate a subsequent transaction, contact: Name: _____ Telephone Number: _____ Email address: _____

Signature (authorized to bind the company)

Print Name and Title

Date

Page _____ of _____

*Reference Number may be an invoice, purchase order, shipping document number or similar unique identifier for the transaction.

INSTRUCTIONS

The Repackager completing the form identifies itself at the top of the form.

The prescription drug being sold or distributed by the repackager is identified with the drug name, strength, dosage form and container size of the repackager's product.

The name of the manufacturer or repackager that is printed on the label of the container is disclosed.

The NDC on the repackaged container may be provided. This element is optional.

The repackager lists its lot number(s) and quantity by lot number. When the repackager has assigned a unique serial number as provided in section 499.003(31), Florida Statutes, this number (or series of numbers) is to be included on the pedigree form.

The Reference Number, Document Type, and Reference Date relate to the sales or distribution document for the prescription drug for which this pedigree is prepared. The reference number should be an invoice or shipping document number when available. If the pedigree is prepared before these numbers are known, the customer's purchase order number may be provided in lieu of the repackager's invoice or shipping number. The document type describes which document number is provided, either an invoice number, shipping number or purchase order number.

Each unit of a prescription drug that went into the repackager's lot must be identified and the pedigree history provided for each unit. If multiple units all have the same history, they may be combined on one pedigree form.

Each lot number and the quantity by lot number, or when the manufacturer has assigned a unique serial number as provided in section 499.003(31), Florida Statutes, the serial number (or series of numbers), are to be included on the pedigree form. Identify the manufacturer and information about the manufacturer to facilitate a subsequent person in the drug's supply chain authenticating the initial sale / distribution with the manufacturer. Provide the NDC number.

The left side of the large box provides information about the owner of the prescription drugs. The right side of the large box provides information about the physical distribution of the prescription drug. If the owner possesses the prescription drugs, then the right side may be left blank.

1. Left side: Tracks the ownership of the prescription drug.

Identify the name and address of the wholesaler or repackager that purchased that (those) lot number(s) or serial number(s) directly from the manufacturer. Provide the Reference Number, Document Type, and Reference Date related to the sale of the prescription drug that was repackaged. The reference number should be an invoice or shipping document number when available for #1's purchase from the manufacturer. If the pedigree is prepared before these numbers are known, the purchase order number may be provided in lieu of the invoice or shipping number. The document type describes which document number is provided; either an invoice number,

shipping number or purchase order number. Print the name of the recipient of the prescription drug at the owner's establishment and provide the recipient's signature if the owner received the prescription drugs. If another person or address received the prescription drugs, this may be left blank but the right side of the form will be completed. Provide a name, telephone number, and email address for a subsequent person in the drug's supply chain to use to authenticate the next wholesale distribution of the prescription drug in the supply chain.

1. Right side: Tracks the physical distribution of the prescription drug and must only be completed in those instances where the owner's establishment does not take physical possession of the prescription drug.

Identify the name and address of the wholesaler or repackager that physically received that (those) lot number(s) or serial number(s) directly from the manufacturer. Provide the Reference Number, Document Type, and Reference Date related to the acquisition of the prescription drug that was eventually repackaged. The reference number should be an invoice or shipping document number when available for #1's receipt of the prescription drug from the manufacturer. If the pedigree is prepared before these numbers are known, the purchase order number may be provided in lieu of the invoice or shipping number. The document type describes which document number is provided; either an invoice number, shipping number or purchase order number. Print the name of the recipient of the prescription drug at the establishment and provide the recipient's signature. Provide a name, telephone number, and email address for a subsequent person in the drug's supply chain to use to authenticate the next wholesale distribution of the prescription drug in the supply chain.

2. Only required to be completed if the repackager did not purchase and receive the prescription drugs there were prepackaged from the manufacturer. Follow the directions for #1 right side and left side above except the reference numbers / dates relate to #2's acquisition of the prescription drug from #1. Provide the name and signature of the person who authenticated all prior transactions. REPEAT the information requested under #2 as applicable for each wholesale distribution of the prescription drug until it reached the repackager.

A responsible person at the repackager must sign and provide his / her name, title, and date signed that the pedigree is accurate and complete.

Indicate whether multiple pages are included with the pedigree. Each pedigree page must be signed.