

(Wholesaler's name)

PRESCRIPTION (LEGEND) DRUG PEDIGREE
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 (optional): _____

Table with 3 columns: Lot Number, Quantity, Unique Serial #

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

OWNERSHIP HISTORY

PHYSICAL DISTRIBUTION HISTORY
(if different from the owner information)

Manufacturer's Name: _____

Manufacturer's information for authentication: _____

1. Wholesaler that purchased from the MANUFACTURER or a REPACKAGER (which requires authentication)

Main pedigree form with multiple sections for ownership and physical distribution history, including fields for Name, Address, Date Purchased, Recipient Name, Signatures, and Contact Information.

I swear or affirm that the information contained on this pedigree is accurate and complete and that prior sales and distributions have been authenticated, if required.

Signature (authorized to bind the company) _____ Print Name and Title _____ Date _____

* Reference Number should be identified as an invoice, purchase order, shipping document number or similar unique identifier.
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INSTRUCTIONS

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

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

If the prescription drug has been repackaged, check this box. The pedigree must trace the repackaged drug back to the manufacturer.

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

The wholesaler lists the lot number(s) and quantity by lot number. When the manufacturer or 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 shipped 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 wholesaler's invoice or shipping number. The document type describes which document number is provided, either an invoice number, shipping number or purchase order number.

Identify the manufacturer or distributor reflected on the label of the prescription drug and information about the manufacturer/distributor to facilitate a subsequent person in the drug's supply chain authenticating the initial sale/distribution with the manufacturer.

The left side of the pedigree provides information about the owner of the prescription drugs. The right side of the pedigree 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: Identify the name and address of the wholesaler that purchased the prescription drug from the manufacturer or if the drug was repacked, the name and address of the wholesaler that purchased the prescription drug from the repackager. Provide the Reference Number, Document Type, and Reference Date related to the purchase of the prescription drug available. If the pedigree is prepared before these numbers are known, the purchase order number may be provided in lieu of the manufacturer's or 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. 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. If this prescription drug was purchased from a repackager, then wholesaler #1 had to authenticate all prior transactions related to the prescription drug on the pedigree received from the repackager. Provide the name and signature of the person who authenticated these transactions. 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: 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 that physically received the prescription drug from the manufacturer or if the drug was repacked, the name and address of the wholesaler that received the prescription drug from the repackager. Provide the Reference Number, Document Type, and Reference Date related to the acquisition of the prescription drug. The reference number should be an invoice or shipping document number when available for #1's receipt of the prescription drug from the manufacturer or repackager. If the pedigree is prepared before these numbers are known, the owner's 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 of the authenticator. 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. 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 form #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 wholesaler preparing this pedigree.

A responsible person at the wholesaler 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.

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