

ALABAMA BOARD OF PHARMACY

SUSAN ALVERSON R.Ph.
Executive Secretary

Location:

111 Village Street
Birmingham, AL 35242

205) 981-2280
(205) 981-2330 Fax
www.albop.com



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August 30, 2016

The FDA is requiring that to be in compliance with the Drug Safety Compliance and Security Act (DSCSA), each state must license Manufacturers, Wholesaler/Distributors, Third-Party Logistics Provider (3PL), Repackagers, and Virtual Manufacturers/ Virtual Distributors. These permits will replace our current Manufacturer/Wholesaler/Distributor permits. We are now required to conduct annual registration of these designated businesses. Renewals for these permits will begin September 1, 2016.

When you log into our website to begin your renewal process you will be able to select from the following license types: Manufacturer, Manufacturer Virtual, Manufacturer Oxygen, Manufacturer Precursor, Wholesaler, Wholesaler Virtual, Wholesaler Oxygen, Wholesaler Precursor, Wholesaler Reverse Distributor, Repackager, Repackager Precursor, 3PL (Third Party Logistics). In order to help you identify which category relates to your business, definitions are listed below.

“Manufacturer” means a person engaged in the manufacturing preparing, propagating, processing, testing and quality control, packaging, repackaging, distributing, or labeling of a prescription drug/device.

Manufacturer Renewal Checklist:

- Discipline since last renewal
- FDA registration with DECRS and/or Establishment Registration & Device Listing
- If out of state Home State License or proof of exemption
- If out of state license verification
- If out of state, copy of Registration with Alabama Secretary of State
- DEA certificate for controlled substance (If Precursor must have Precursor DEA certificate)

“Wholesale Distribution” means distribution of prescription drugs/devices to a person other than a consumer or patient, but does not include:

- 1) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of these regulations “emergency medical reasons” includes transfers of prescription drugs from one permitted facility to another permitted facility to alleviate a temporary shortage;
- 2) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

- 3) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;
- 4) The sale, purchase, or trade of blood and blood components intended for transfusion;
- 5) The purchase of other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations.
- 6) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals that are under common control; for purposes of these regulations, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;
- 7) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501© (3) of the U.S. Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- 8) Any entity that distributes prescription drugs or controlled substances into the state must hold a permit by the Alabama State Board of Pharmacy
- 9) The sale/purchase of a prescription drug by a retail pharmacy to other retail pharmacies or to a licensed practitioner for office use, if the total annual dollar volume of these sales/purchases does not exceed (5%) of that pharmacy's total annual prescription drug sales.

Wholesale Distributor Renewal Checklist:

- Discipline since last renewal
- FDA registration on the Wholesale Distributor and Third-Party Logistics Providers Reporting and/or Establishment Registration & Device Listing
- If out of state Home State License or proof of exemption
- If out of state license verification
- If out of state copy of Registration with Alabama Secretary of State
- DEA certificate for controlled substance (If Precursor must have Precursor DEA certificate)

"Third-Party Logistics Provide (3PL)" shall mean any person that provides or coordinates warehousing, transport or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

3PL Renewal Checklist:

- Discipline since last renewal
- FDA registration on the Wholesale Distributor and Third-Party Logistics Providers Reporting
- If out of state Home State License or proof of exemption
- If out of state license verification
- If out of state copy of Registration with Alabama Secretary of State
- DEA certificate for controlled substance

“Repackager” means a person registered by the US Food and Drug Administration as a repackager who removes a prescription drug/device product from its marketed container and places it into another, usually of a smaller size, without further manipulation of the drug to be distributed to persons other than the consumer.

Repackager Renewal Checklist

- Discipline since last renewal
- FDA registration DECRS and/or Establishment Registration & Device Listing
- If out of state Home State License or proof of exemption
- If out of state license verification
- If out of state copy of Registration with Alabama Secretary of State
- DEA certificate for controlled substance (If Precursor must have Precursor DEA certificate)

“Reverse Distributor” means any Person who receives, takes inventory, and manages the disposition of outdated, expired, or otherwise non-saleable Drugs from Pharmacies, Wholesale Distributors, or other entities.

Reverse Distributor Checklist for Renewal:

- Discipline since last renewal
- If out of state Home State License or proof of exemption
- If out of state license verification
- If out of state copy of Registration with Alabama Secretary of State

“Virtual Wholesale Distributor” means any entity engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the State which: Entity does not own NDA or ANDA and does not take physical possession of products; however, purchases the drug or device from a Manufacturer and must be registered as a business entity with the FDA and must operate out of a commercial facility and not out of a residence or personal dwelling..

Virtual Wholesale Distributor Renewal Checklist:

- Discipline since last renewal
- FDA registration of entity –labeller code not acceptable (DECRS)
- Agreement with contract manufacturers and 3PL (1st page and signature page of agreement)
- If out of state Home State License or proof of exemption
- If out of state license verification
- If out of state copy of Registration with Alabama Secretary of State

“Virtual Manufacturer” means an entity that owns the NDA and ANDA but does not take physical possession of the drug or device. Entity contracts with a contract manufacturing organization for the physical manufacture of the drug or device and is not involved in the physical manufacture of the drug or device.

Virtual Checklist for Renewal:

- Discipline since last renewal
- FDA registration of entity –labeller code not acceptable (DECRS)
- Agreement with contract manufacturers and 3PLs (1st page and signature page of agreement)
- If out of state Home State License or proof of exemption
- If out of state license verification
- If out of state copy of Registration with Alabama Secretary of State

Annual registration will be \$500 per year. Controlled substance licenses are \$600 annually.

If you are a manufacturer, wholesaler, 3PL, repackager or virtual, you must also register with the FDA.

Sincerely,

A handwritten signature in black ink that reads "Susan F. Alverson". The signature is written in a cursive style with a large, sweeping initial "S".

Susan Alverson, R.Ph