



FDA Listing Inc.

REGISTRATION & LISTING REQUIREMENTS FOR THE MANUFACTURE OR DISTRIBUTION OF HUMAN DRUGS		
TYPE OF FIRM	REGISTRATION STATUS	LISTING STATUS
<i>Manufacturer [including homeopathic & controlled drugs]</i>	Yes	Yes
<i>Contract Manufacturer</i>	Yes	Yes
<i>Own Label Distributor</i>	No	Yes
<i>Wholesale Distributor</i>	Yes	No
<i>Own Label Repacker</i>	Yes	Yes
<i>Own Label Relabeler</i>	Yes	Yes
<i>Contract Relabeler</i>	Yes	Yes
<i>Contract Testing Laboratory [dosage forms & active ingredient release]</i>	Yes	No
<i>Contract Testing Lab [doing non-release tests]</i>	No	No
<i>Contract Sub-Manufacturer</i>	Yes	Yes
<i>IND Manufacturer [Clinical Drugs]</i>	No	No
<i>NDA and ANDA Manufacturer</i>	Yes	Yes
<i>Sponsor/Monitors/Clinical Investigator</i>	No	No
<i>Contract Sterilizer</i>	Yes	Yes
<i>Fulfillment Packager [adding substantive labeling]</i>	Yes	Yes
<i>Mail Order House [adding insubstantial labeling]</i>	No	No
<i>Printing House</i>	No	No
<i>Medical Gas Transfiller</i>	Yes	Yes
<i>First Aid/Rescue Squad [transfilling for own use]</i>	No	No
<i>Medical Gas Transfiller [operating out of a van]</i>	Yes	Yes
<i>Contract Assembler</i>	Yes	No
<i>Active Drug Substance Manufacturer</i>	Yes	Yes
<i>Excipient Drug Manufacturer</i>	No	No
<i>Manufacturer of Research Drugs</i>	No	No
<i>Drug Importer</i>	No	No
<i>Foreign Drug Manufacturer</i>	Yes	Yes
<i>Methadone Clinic</i>	No	No
<i>Retail Pharmacy</i>	No	No
<i>Salvage Operation</i>	Yes	No
<i>Biopharmaceutical Clinical Facility</i>	No	No
<i>Outsourcing Facility</i>	Yes	No