

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REGISTRATION OF DRUG ESTABLISHMENT/ LABELER CODE ASSIGNMENT (In accordance with Public Law 92-387)				FDA USE ONLY	FDA USE ONLY
NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than \$1,000, or both. (FD&C Act, Section 303).				LABELER CODE	REGISTRATION NUMBER
SECTION A - SITE INFORMATION					
REPORTING FIRM NAME				STATE OF INC.	
SITE ADDRESS (No P.O. Box)				SITE TELEPHONE NUMBER ()	
CITY	STATE	ZIP CODE	COUNTRY	BUSINESS CATEGORY <input type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY	
SITE MAILING ADDRESS (If different from site address)					
CITY	STATE	ZIP CODE	COUNTRY	SITE INTERNET/EMAIL ADDRESS	
DOING BUSINESS AS (DBA) NAME OF FIRM (if applicable)					
PARENT COMPANY NAME					
REASON(s) FOR SUBMISSION <input type="checkbox"/> Firm Registration <input type="checkbox"/> Registration of Additional Site <input type="checkbox"/> Re-Registration <input type="checkbox"/> LC Assignment <input type="checkbox"/> Name Change		TYPE OF OWNERSHIP <input type="checkbox"/> Sole Proprietorship <input type="checkbox"/> Partnership <input type="checkbox"/> Coop. Assn. <input type="checkbox"/> Corporation <input type="checkbox"/> Other _____		PERSON SUBMITTING DATA AND TELEPHONE BUSINESS TYPE <input type="checkbox"/> Manufacturer <input type="checkbox"/> Repacker <input type="checkbox"/> Relabeler	
<input type="checkbox"/> Address Change <input type="checkbox"/> Merger/Buyout <input type="checkbox"/> Reentry into Business with Same Name <input type="checkbox"/> Out of Business				<input type="checkbox"/> Distributor* <input type="checkbox"/> Foreign Country <input type="checkbox"/> Analytical Lab <input type="checkbox"/> Other _____	
SECTION B - FIRM COMPLIANCE MAILING ADDRESS for Annual Listing Report and/or Firm Correspondence					
NUMBER AND STREET AND/OR P.O. BOX and ATTENTION LINE and/or Internal Mail Code				TELEPHONE NUMBER ()	
CITY	STATE	ZIP CODE	COUNTRY	COMPLIANCE INTERNET/EMAIL ADDRESS	
SECTION C - ADDITIONAL FIRM AND SITE INFORMATION					
NAME OF OWNER, PARTNERS OR OFFICERS		TITLE		POSITION	
OTHER FIRMS DOING BUSINESS AT THIS SITE					
LABELER CODE	FIRM NAME		LABELER CODE	FIRM NAME	
SECTION D - SIGNATURE					
SIGNATURE OF AUTHORIZING OFFICIAL			TITLE		DATE
RETURN THIS FORM TO: FOOD AND DRUG ADMINISTRATION CDER/DRUG REGISTRATION AND LISTING (HFD-337) 5600 FISHERS LANE ROCKVILLE, MD 20857 INTERNET: DRLS@FDA.HHS.GOV			SIGNATURE OF DISTRIBUTOR		
			DISTRIBUTOR'S TELEPHONE NUMBER ()		

*DISTRIBUTOR'S CERTIFICATION: As a, Distributor, I am submitting product listing information to the FDA on my own behalf. I have provided a copy of this certification (Form FDA 2656) to the registered manufacturer(s). My signature and phone number are listed below.

If using Federal Express, DHL or any special carrier to return the forms, please use the following address:

(Please refer to the Drug Registration and Listing Instruction Booklet.)

When completing this form, please refer to the Drug Registration and Listing Instruction Booklet for assistance.
PLEASE PRINT IN ENGLISH USING **BLACK** INK.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDER/Drug Registration and Listing (HFD-337)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.