LifeScience Logistics			
Title:	Prescription Drug Relabeling Requirements and Process		
Number:	WI 600.09	**Rev. Date:**	07-NOV-2023
Rev. Level:	002		

1.0 PURPOSE

The purpose of this document is to define the process for relabeling Canadian-approved drug product that has been imported into the U.S. under Section 804 of the Food, Drug and Cosmetic Act, also known as the Canadian Prescription Drug Product Importation Program.

2.0 SCOPE

This procedure is applicable to any facility where the relabeling of drug product is either coordinated or conducted.

Activities not consistent or pertinent to the relabeling of drug product are out of scope.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality Systems Regulations
SOP 1800	Training and Qualification
SOP 1101	Control of Records
SOP 1100	Document Control
SOP 1351	Deviation/CAPA – RX
WI 600.05	Prescription Drug Receiving
WI 600.06	Prescription Drug Hold and Release
WI 600.09.01	NDC Product Sampling and Approval Form Template
WI 600.10	Prescription Drug Pick/Pack/Ship
WI 600.27	Prescription Drug Vendor Returns and Quarantine Shipping

4.0 DEFINITIONS

Rev. Level	Initial documents start at revision number 000. As changes are made to the document, the revision number is raised sequentially by whole numbers.
Product Identifier	A standardized graphic that includes, in both human-readable form and on a machine-readable data carrier (2-dimensional data matrix barcode) that conforms to the standards developed by a widely recognized international standards development organization: • The standardized numerical identifier, • The lot number, and • The expiration date of the product.
Standardized Numerical Identifier	A set of numbers or characters used to uniquely identify each package or homogenous case. The Standardized Numerical Identifier combines: • The NDC that corresponds to the specific product (including the particular package configuration); and A unique alphanumeric serial number of up to 20 characters.

LifeScience Logistics			
Title:	Prescription Drug Relabeling Requirements and Process		
Number:	WI 600.09	**Rev. Date:**	04-Aug-2023
Rev. Level:	001		

10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Read and Understand – Self Training	☐ Read and Exhibit Competency – Trainer Led with Module/Assessment when applicable	☐ Instructor Led – Trainer Led with Module/Assessment when applicable

Procedure Name or Description of Training	Procedure Number	Revision Level

Trainee: Signature and date indicates you have trained and understand this procedure and all associated documents as well as the training module/material listed above.

Trainee Printed Name	Trainee Signature	Department	Date

Trainer: Signature below indicates you have presented training on procedure listed above and confirm all listed employees completed training as defined.

Document Training Number / Training Session	Trainer Printed Name (N/A if Self-Training)	Trainer Signature (N/A if Self-Training)