



INSPECTION AGENDA - RETAIL OUTLET FOR NON-PRESCRIPTION DRUGS (RONPD)

Inspection Activity

I. Opening Meeting

- Introductions / Inspection scope/Attendance record

II. Ocular inspection of Premises / Storage facilities and Products

- Storage and sanitary conditions
- Segregated area for expired, damaged, recalled or returned products
- Product compliance to registration and labeling requirements – may collect product (All pharmaceutical products must be OTC)

III. Document and Records Review

- License to Operate
- Pharmacist's credentials
- List of all RONPDs supervised by the pharmacist with corresponding schedule
- Attendance to FDA licensing seminar
- Risk Management Plan
- Standard Operating Procedures (SOPs)
- Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
- Franchise agreement (if applicable)

IV. Report Writing

- Consolidation of findings; when necessary

V. Exit Meeting

- Attendance record /Discussion of findings or deficiencies /violation