CHECKLIST OF REQUIREMENTS FOR OPENING
OF DRUGS / COSMETICS ESTABLISHMENTS

For Pre-application as Manufacturer/Repacker:
  ____1. Submit Letter of Intent for pre-site inspection (Fee: P500)

GENERAL REQUIREMENTS:
  ____1. Information as to activity(ies) of establishment
  ____2. Notarized Accomplished Petition Form/Joint Affidavit of Undertaking
  ____3. Photocopy of Business Name Registration
     a. For single proprietorship, registration from the Department of Trade & Industry (DTI)
     b. For corporation/partnership, registration form the Securities & Exchange Commission (SEC) and Articles of Incorporation
     c. For Cooperative, registration from the Cooperative Development Authority

Note:  
  a. If the registered address with DTI/SEC is different from the address of the establishment to be licensed, submit a photocopy of the Business/Mayor’s Permit
  b. If the establishment adopts another business name style different from the corporation name, the business/trade name shall be indicated in the SEC registration certificate.

  ____4. ID pictures of the Owner /Authorized Representative and Pharmacist (size: 5cm x 5xm)
  ____5. Photocopy of Pharmacist’s Registration Board Certificate, PRC ID and PTR
  ____6. Photocopy of Certificate of FDA Seminar on Licensing of Establishment by the pharmacist
  ____7. Photocopy of notarized valid Contract of Lease of the space/building occupied (if the space/bldg. is not owned)
     If owned, copy of TCT (Transfer Certificate Title)
  ____8. Photocopy of Financial Statement duly notarized or received by Bureau of Internal Revenue (BIR), if not available, submit notarized certification of initial capital invested
  ____9. Location Plan/Site (indicate size, location, immediate environment, type of building)
  ____10. List of products to be manufactured/distributed in generic and brand names (indicate dosage form and strength)
  ____11. Duties and responsibilities of the pharmacist
  ____12. Pharmacist Clearance
  ____13. Reference Books:
     a. USP/NF (latest edition)
     c. Remington’s Pharmaceutical Sciences (latest edition)
     d. Goodman & Gilman Pharmaceutical Basis of Therapeutics
     e. British Pharmacopoeia (BP)
     f. Philippine National Drug Formulary
     g. Philippine Pharmacopoeia

*For Drugs - a & b (mandatory) and any reference from c - g
*For Cosmetics – b, other official monographs, if applicable (e.g. USP, BP) and other FDA regulation

ADDITIONAL REQUIREMENTS:

I.  A For Manufacturer:
    ____1. Site Master File (SMF)

B. For Repacker:
    ____1. Site Master File (SMF)
    ____2. Notarized valid Contract/Agreement with the Manufacturer with stipulation that both the Manufacturer and Repacker are jointly responsible for the quality of the products

C. For Trader:
    ____1. Notarized valid Contract/Agreement with the manufacturer with stipulation that both the Manufacturer and Trader are jointly responsible for the quality of the products and statement of ownership of formulation
    ____2. Floor plan of office and storage area

D. For Importer of Raw Materials/Finished Products in Bulk:
    ____1. Foreign Agency Agreement duly authenticated by the Territorial Philippine Consulate
    ____2. Certificate of Status of Manufacturer (CGMP Certificate) issued by a Government Health Agency duly authenticated by the Territorial Philippine Consulate (for API, finished cosmetics product/s)
    ____3. Certificate of Analysis (Raw Materials, Finished Products)
    ____4. Material Safety Data Sheet (MSDS)

Note:  Notarized certificate authorizing the person who signed in behalf of the establishment/company if he/she is not owner or one of the incorporators as registered with DTI/SEC

FEES: See Schedule of Fees of LTO at the back page

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### SCHEDULE OF FEES
**DRUGS/COSMETICS MANUFACTURER/TRADER**
**PER A.O. 50 s. 2001**

<table>
<thead>
<tr>
<th>CAPITAL INVESTMENT</th>
<th>COMPANY CLASSIFICATION</th>
<th>CORRESPONDING FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Based on Financial Statement)</td>
<td></td>
<td></td>
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<tr>
<td>20 Million and below</td>
<td>Drug Manufacturer</td>
<td>₱ 10,000.00</td>
</tr>
<tr>
<td></td>
<td>Cosmetic Laboratory</td>
<td>₱ 5,000.00</td>
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<tr>
<td></td>
<td>Medical Device Manufacturer</td>
<td>₱ 5,000.00</td>
</tr>
<tr>
<td></td>
<td>Drug/Cosmetic/Medical Device Trader</td>
<td>₱ 3,000.00</td>
</tr>
<tr>
<td>Over 20 Million but below 50 Million</td>
<td>Drug Manufacturer</td>
<td>₱ 15,000.00</td>
</tr>
<tr>
<td></td>
<td>Cosmetic Laboratory</td>
<td>₱ 10,000.00</td>
</tr>
<tr>
<td></td>
<td>Medical Device Manufacturer</td>
<td>₱ 7,000.00</td>
</tr>
<tr>
<td></td>
<td>Drug/Cosmetic/Medical Device Trader</td>
<td>₱ 5,000.00</td>
</tr>
<tr>
<td>50 Million and above</td>
<td>Drug Manufacturer</td>
<td>₱ 20,000.00</td>
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<tr>
<td></td>
<td>Cosmetic Laboratory</td>
<td>₱ 15,000.00</td>
</tr>
<tr>
<td></td>
<td>Medical Device Manufacturer</td>
<td>₱ 10,000.00</td>
</tr>
<tr>
<td></td>
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<td>₱ 7,000.00</td>
</tr>
</tbody>
</table>

### SCHEDULE FOR SUBMISSION OF APPLICATION
- **MONDAY** – FOOD
- **TUESDAY** – DRUGS
- **WEDNESDAY** – DRUGS
- **THURSDAY** – COSMETICS / HHS