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| Republic of the PhilippinesDepartment of Health**FOOD AND DRUG ADMINISTRATION****CENTER FOR DRUG REGULATION AND RESEARCH****DRUG MANUFACTURER ([ ] ) / PACKER ([ ] ) / REPACKER ([ ] ) TRADER ([ ] )****SELF-ASSESSMENT TOOLKIT FORM****CHANGE OF OWNERSHIP** |
| **COMPANY NAME** | **:** |  |  |
| **COMPANY ADDRESS** | **:** |  |  |
|  |  |
| **PREVIOUS OWNER** | **:** |  |  |
| **NEW OWNER** | **:** |  |  |
| **LTO NUMBER** | **:** |  |  |
| **VALIDITY** | **:** |  |  |
| **Directions:****Fill out the form by ticking the applicable box. Provide remarks on the client’s column when necessary.****Submit in Portable Document Format (pdf) and word format duly signed by the pharmacist/owner.** |
| **DOCUMENTARY REQUIREMENTS:** | Yes | No | **REMARKS** |
|  |  | **CLIENT** | **FDA** |
| 1. **Application Form**
 |
| * *Is the integrated application form properly filled out?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Is it duly notarized?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Are the signatories in the application form the authorized persons as required under the following circumstances?*
 |  |
| 1. If single proprietorship – the owner as registered in DTI (unless there is a different authorized person)
 | **[ ]**  | **[ ]**  |  |  |
| 1. If partnership/corporation – one of the incorporators or authorized person as indicated in the board resolution or Secretary’s Certificate
 | **[ ]**  | **[ ]**  |  |  |
| 1. If cooperative – authorized person indicated in the board resolution or Secretary’s Certificate of the cooperative
 | **[ ]**  | **[ ]**  |  |  |
| If the signatory is not the owner or one of the incorporators, as the case may be: |  |
| * *Is there a board resolution or notarized Secretary’s Certificate clearly identifying the person authorized to sign for and in behalf of the owner or corporation submitted?*
 | **[ ]**  | **[ ]**  |  |  |
|  |
| 1. **Proof of business name registration**
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| 1. For single proprietorship, Certificate of Business Registration issued by the Department of Trade and Industry (DTI)
 |  |
| * *Is the business name applied for LTO the same with that of DTI registration certificate?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Is the DTI certificate still valid?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Is the owner appearing in the application form the same with that of the DTI certificate?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Is the address of the establishment applying for LTO within the territorial coverage?* *If the business address indicated in DTI is different from the exact address as declared in the application form, is there a clear copy of* ***Business/Mayor’s Permit or Barangay clearance*** *indicating the complete address of drug establishment?*
 | **[ ]**  | **[ ]**  |  |  |
| 1. For corporation, partnership and other juridical person, Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation
 |  |
| * *Is the business name applied for LTO the same with that of the SEC registration certificate?* *If the company uses another business name style different from its corporate name, is an amended SEC registration reflecting the same submitted?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Is the address indicated in the SEC the same with the address of the establishment applied for LTO?*
 | **[ ]**  | **[ ]**  |  |  |
| * + *If the address in SEC is still occupied but the business operation applied for LTO is located in a separate area, is a clear scanned copy of Business/Mayor’s Permit or Barangay clearance indicating the complete address of drug establishment submitted?*
 | **[ ]**  | **[ ]**  |  |  |
| * + *If the address in SEC is no longer occupied, is an amended SEC registration reflecting the current business address submitted?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Is the type of activity and product applied for LTO indicated in the Articles of Incorporation (Article II)?*
 | **[ ]**  | **[ ]**  |  |  |
| 1. For cooperative, Certificate of Registration issued by the Cooperative Development Authority and the approved by-laws
 |  |
| * *Is the business name applied for LTO the same with that of the CDA registration certificate?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Is the address indicated in the CDA the same with the address of the establishment applied for LTO?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Is the type of activity and product applied for LTO indicated in the approved articles and by-laws of the cooperative?*
 | **[ ]**  | **[ ]**  |  |  |
| 1. For government-owned or controlled corporation
 |  |
| * *Is there a copy of the law creating the same? (if with original charter)*
 | **[ ]**  | **[ ]**  |  |  |
|  |
| 1. **Deed of sale or transfer of rights**
 |
| * *Is it duly notarized?*
 | **[ ]**  | **[ ]**  |  |  |
| * *Are the previous and new owners correctly identified?*
 | **[ ]**  | **[ ]**  |  |  |
|  |
| 1. **Proof of Payment**
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| * *Is the payment made according to the required fee*?
 | **[ ]**  | **[ ]**  |  |  |
| * *Is there a scanned copy of proof of payment (e.g FDA official receipt, Landbank On-coll validated slip) submitted?*
 | **[ ]**  | **[ ]**  |  |  |
| *Note: If the following is/are not submitted in the initial application, the said document/s shall be attached:** *Risk Management Plan (RMP) or commitment letter while the official RMP framework from FDA is not yet issued*
* *GPS Coordinates*
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| ***NOTE: ADDITIONAL DOCUMENTS MAY BE REQUIRED TO BE SUBMITTED AS DEEMED NECESSARY.*** |
| *--- To be filled out by client: ---* |
| Prepared by: |  | Signature: |  |
| Position (Pharmacist / Owner): |  | Date: |  |
| *--- To be filled out by RFO: ---* |
| **Decision:** | **Remarks:** |
| Approval | **[ ]**  |
| Denial | **[ ]**  |
| Clarification | **[ ]**  |
| Inspection | **[ ]**  | Evaluated by: |  | Date: |  |
| *--- To be filled out by CDRR: ---* |
| **Decision:** | **Remarks:**       |
| Approval | **[ ]**  |
| Clarification | **[ ]**  |
| Evaluated by: |  | Date: |  |