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| Republic of the Philippines  Department 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** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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?* | | | | | | | | | | |  | | | | |  | | |  | | | | | | | | |  | | |
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| 1. **Proof of Payment** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * *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* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ***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: | | |  | | | | | | |