

FDA ADVISORY
No. **2024-0639**

15 APR 2024

TO : ALL REGISTERED PHARMACISTS OF LICENSED DRUG ESTABLISHMENTS

SUBJECT : Clarification on the Requirements for Change of Qualified Person Initially Registered in a Licensed Drug Establishment

Section V.B.3.C of FDA Circular No. 2020-030, entitled "Guideline for the Use of the FDA eServices Portal System for License to Operate (LTO) Application of Drug Distributors, Drug Traders, Drugstores, Retail Outlets for Non-Prescription Drugs (RONPD), Contract Research Organizations (CRO) and Sponsors" under Change of Qualified Person initially registered with the FDA requires a Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment.

As such, verification of the Pharmacist as the Qualified Person is imperative, including registration, based on FDA records, with any drug establishment licensed with the FDA.

However, there are instances where the Pharmacist cannot provide a resignation letter duly signed by the former employer due to some reasons, resulting to non-acceptance of the LTO application.

In view of the foregoing, all concerned Pharmacists who are applying as the Qualified Person of a drug establishment are hereby advised that submission of a duly **notarized Affidavit of Undertaking** as an alternative document shall be accepted under the following circumstances:

1. If the Pharmacist cannot provide a resignation letter duly acknowledged/noted by the former employer due to personal issues or differences which caused the refusal of the employer to accept the pharmacist's resignation;
2. When the Pharmacist vehemently denies that he/she has never been employed or connected to any drug establishment;
3. When the Pharmacist claims that he/she has initially applied to be the company's registered Pharmacist but later decided to withdraw her license without her knowing that her license has been used by the said company; or
4. Such other circumstances as maybe determined by the FDA.

For information of all concerned stakeholders.



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Director General

