

Annex B

Consolidated Question and Answers on FDA Circular No. 2022-010

Question	Answers
Will the video recording and presentation be readily available for public viewing?	The Center will be sharing the edited video recording and presentation for the ease of stakeholders' viewing in the coming weeks. Announcements will be made through the FDA website.
Why is the pilot implementation designated solely for National Capital Region (NCR)?	<p>The pilot implementation for the first six (6) months is intended for NCR to ensure that the system, eServices Portal System, is ready and for immediate resolution will be provided for possible bugs and system issues. Furthermore, the covered area or region for the said pilot implementation was based on the survey conducted from 6 October to 7 November 2022.</p> <p>Please be reminded that during the 2-years transitory period, securing an LTO is voluntary.</p>
Does the FDA have an upcoming schedule of PCO trainings? Can we apply for a training accreditation as well?	<p>The implementing guidelines for the certification of SPH and PH, and the accreditation for training providers will have a separate issuance. Currently, this issuance is under development.</p> <p>For the meantime, stakeholders seeking an LTO with the FDA, pursuant to FDA Circular No. 2022-010, are allowed to submit training attendance and/or certificates conducted by FPA accredited training providers and FPA certified pesticide applicators.</p>
What is the FDA definition of branch office for purposes of having a SPH?	A branch office is the extension of the main office, both of which are considered as a single legal entity and performs the same activity as the main office.
Is it necessary to have a business permit from LGU's to be classified as a branch office?	The business permit for the branch office is required. However, the FDA will only issue a single LTO for main office and branch office as long as it is considered as single legal entity and performs the same activity.
Is a halfway house/staff house considered as branch office?	If it is used as storage facility, this will be classified as warehouse which shall also be declared on the LTO application. However, if it fulfils the condition of a branch office, it may then be classified as a branch office.
Will there be an FDA designated office or person to handle all FDA Circular 2022-010 implementation related inquiries?	For now, all inquiries relative to PCO licensing may be sent to the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) email address: cchuhsrr.lrd.hup@fda.gov.ph
Can a single LTO application select multiple scope of work?	Applicants may select restricted to one scope of work per application. Applicants are thus advised to refer to Section 4 C and D of FDA Circular No. 2022-010 on the definitions provided to appropriately select the scope of work and method of application.
Will the FDA recognize the licensure training conducted by FPA last November 2007?	The FDA Circular No. 2016-008 recognizes licenses and identification cards issued by FPA before November 2007. Following the issuance of FDA Circular No. 2022-010, stakeholders are advised to seek the appropriate qualifications in accordance to the new rules and regulations.
Where can we report unlicensed / fly-by-night PCOs? Will there be penalties or fine?	It is clarified that for the 2-year transitory period, an FDA-issued LTO remains to be voluntary. The absence of an LTO during the said period, hence, is not yet considered as a violation against FDA Circular No. 2022-010. However, should there be any safety concerns, reports may be sent to ereport@fda.gov.ph .
Is there a certain template / format for the documentary requirements (e.g., notarized agreement, DOH contract for medical)?	As of now, the FDA does not have a template / format for documentary requirements, rather the details contained in the agreement are enumerated in the FDA Circular.

How many times will a certain PCO be allowed to reapply for LTO?	One application at a time. Please wait for the final recommendation of the pre-assessment before proceeding with a new or different application.
It is noted that a single branch office may be declared during the initial application, what will be the process for multiple branch offices?	The addition of branch offices is through the submission of a major variation application. For the meantime, the applicant may only declare a single branch office during the initial application. Once the system is ready and capable to receive variation applications, it shall be communicated through an advisory.
If the PCO has subsidiary companies, can they also be considered Branch Offices or will they need to file for separate LTOs?	The reference will be the business name registration, which is the SEC. If a single SEC reflects all subsidiaries, it is considered as a single legal entity with multiple subsidiaries and this can be classified as branch office. However, if there are multiple SEC registrations, it is considered as different legal entities.
What will happen if I fail to secure an LTO within the prescribed time period?	After the 2-year transitory period, it is mandatory to secure an LTO. Any PCOs without the required LTO will be in violation of FDA Circular No. 2022-010 and may be subject to appropriate regulatory actions.
When can we apply for a PCO LTO?	The FDA will start receiving PCO LTO applications on 1 February 2023. The first six (6) months of the transitory period shall serve as the pilot implementation solely for NCR. Announcements will be made on the FDA website with regards to the full implementation.
If the authorized personnel is not an SPH, can it be a third party person or consultant instead?	The only authorized representative allowed by the FDA are the following: 1. Owner 2. General Manager 3. CEO 4. President 5. SPH
Where are the specific requirements for SPH and PH?	For the initial LTO application, the requirement when it comes to SPH and PH are the following: 1. Name 2. Valid ID 3. Credentials. For the credentials, please refer to Section V Item B.3 of FDA Circular No. 2022-010. In lieu of FDA certifications, trainings and/or attendance provided by FPA or any reputable organizations within the last 5 years from the issuance of FC 2022-010 is allowed.
What are the accredited payment partnerships of FDA?	The FDA accepted payment channels are enumerated in the Order of Payment. To date, the available payment channels: 1. BancNet Online Bills Payment Facility 2. Land Bank of the Philippines, either Over-the-Counter in any Landbank branch using the Oncoll Payment Slip or through Link.BizPortal
What document can we provide to the client in the light of the 2-year transitory period?	The FDA Circular No. 2022-010, section VI C.2, cited in the transitory provisions that “the transitory period shall serve as moratorium period where no other public or private establishment shall require any FDA LTO prior to the conduct of Pest Control Operations, while covered establishments are in the process of complying with the new guidelines.”
For PCO corporation that is formerly a Sole proprietor, will it be both active due to the transition? What will be the appropriate process?	You may secure the LTO using the SEC business registration (as corporation) after your transition if it occurs before the end of the transitory period and the LTO becomes a mandatory regulatory requirement.

<p>If the PCO is already licensed by the FDA, will there be a need to secure a separate LTO under FPA as well?</p>	<p>Based on the Supreme Court Ruling G.R. No. 161594, the jurisdiction of FPA only extends to agricultural pest control operators/applicators and the jurisdiction over urban pest control has been transferred to FDA.</p> <p>Further, if the pest control activities only involved in the application of pesticides on urban areas (non-agricultural), this is covered by the FDA regulation, not FPA's.</p>
<p>Will the pilot implementation cause a discrimination to PCOs that are not within the NCR?</p>	<p>Following FDA Circular No. 2022-010, section VI C.2, cited in the transitory provisions that “the transitory period shall serve as moratorium period where no other public or private establishment shall require any FDA LTO prior to the conduct of Pest Control Operations, while covered establishments are in the process of complying with the new guidelines.” It is, thus, designed to allow fair treatment across all legitimate PCO establishments regardless of the status of their FDA license.</p> <p>The FDA through CCHUHSRR will endeavor to commence the full implementation as soon as a satisfactory assessment of the pilot implementation has been made.</p>
<p>Can we submit documents for review before we officially lodge our application?</p>	<p>For PCO LTO application, the pre-assessment will serve as the first review on the completeness. Please be reminded that it is the applicants’ responsibility to ensure the correctness of the documentary requirements that will be submitted.</p>
<p>Will there be a set limit on the application disapproval?</p>	<p>The FDA has no limit on the disapproval of applications. However, please be reminded that the payment will be forfeited for disapproved applications. Please be further reminded that it is the responsibility of the applicant to submit the correct and complete documentary requirements.</p>
<p>Will the FDA provide a guide or step by step procedure on securing an LTO?</p>	<p>The FDA will provide a step-by-step procedure in a form of announcement, FDA Advisory and video recording for the benefit of the concerned stakeholders. Please keep yourselves updated through announcements made on the FDA website and FDA Facebook page.</p>
<p>How can the FDA protect the future FDA-licensed operators from unlicensed individuals?</p>	<p>After the 2-year transitory period, it is mandatory to secure an LTO. Any PCOs without the required LTO will be in violation of FDA Circular No. 2022-010 and may be subject to appropriate regulatory actions.</p>
<p>What are the actions of FDA on the HUP products being freely sold online?</p>	<p>The FDA conducts Post Marketing Surveillance activities, such as market collection and ads monitoring which includes online platforms. Thus, appropriate regulatory actions shall be imposed upon erring establishments or individual following due process.</p>
<p>Will the FPA issued LTO still valid even after the 2-year transitory period?</p>	<p>After the 2-year transitory period, it is mandatory for PCO to secure an appropriate authorization from the FDA.</p>
<p>Are the IDs issued by FPA on SPH and PH still valid after the 2-year transitory period?</p>	<p>The FPA-issued IDs will still be recognized as long as there is still no implementing guidelines for the certification of SPH and PH as well as the accreditation of training providers.</p>
<p>Will there be future meeting, consultation, and seminar for PCOs?</p>	<p>The FDA will inform the concerned stakeholders on future PCO related activities through announcements posted on the FDA website and FDA Facebook page.</p>