DUTIES AND RESPONSIBILITIES

Pursuant to Republic Act. No 3720, as amended by Executive Order No. 175 and Republic Act 9711 and its Implementing Rules and Regulations, the herein named Food-Drug Regulation Officer (FDRO) is hereby authorized to:

1. Assume primary jurisdiction in inspecting and evaluating establishments regulated by FDA;
2. Monitor, inspect and evaluate health products and establishments covered by the FDA Act of 2009, its Rules and Regulations, and other relevant laws, for the purpose of the issuance of the necessary authorizations;
3. Enter establishments, and facilities at reasonable hours in which health products are manufactured, processed, packed or held, or to enter any vehicle used to transport products;
4. Inspect, in reasonable manner, such factory, warehouse, establishments, or vehicle and all pertinent equipment, finished or unfinished materials, containers, and labelling therein;
5. Take copies of documents, pictures and voice or video recording whenever necessary, as objective evidence;
6. Collect samples of health products including finished or unfinished materials, containers, and labelling;
7. Recommend for issuance of appropriate authorizations or disapproval of an application for a License to Operate or other related authorization;
8. Issue Certificate of Compliance with technical requirements to serve as basis for the issuance of appropriate authorization and spot check for compliance with regulations regarding operation of establishments;
9. Assess the establishments' intrinsic risk and compliance status;
10. Conduct Post Marketing Surveillance of all health products;
11. Submit a report to serve as basis for the motu proprio action of the Deputy Director-General for Field Regulatory Operations Office, upon finding, in the course of its evaluation, monitoring, inspection and spot checking, of any non-compliance and violation of other requirements required by the FDA, its implementing laws, rules and regulations.
12. Establish and implement a quality system consistent with FDA's mandate;
13. Establish and manage database in relation to their functions, in coordination with the information and Communications Technology Management Division;
14. Review, evaluate, and monitor implementation of Risk Management Plans for conformance with the FDA standards;
15. Liaise with Centers and other offices on inspection-related matters; and
16. Exercise such other powers and perform such other related functions that may be assigned or necessary to carry out the above duties and responsibilities.