Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20230765

05 MAY 2023

TO : **ALL HEALTH PRODUCT ESTABLISHMENTS AND BUSINESS OPERATORS**

SUBJECT : **ENGAGEMENT WITH CONSULTANCY FIRMS TO TRANSACT BUSINESS WITH THE FOOD AND DRUG ADMINISTRATION**

The FDA is aware that there are several companies or individuals offering services related to FDA regulations such as assisting with product approvals or providing advice on regulatory compliance. However, it is important to note that these services are not endorsed or accredited by the FDA.

The agency would like to remind the health product business operators that the **FDA does not accredit, certify or endorse any consultants or consultancy firms**. The agency continuously reviews its policies, issues revised guidelines to ensure business-friendly regulatory processes.

The FDA has issued the Department of Health Administrative Order (DOH AO) No. 2020-0017, entitled "*Revised Guidelines on the Unified Licensing Requirements and Procedures of the FDA Repealing AO NO. 2016-0003*". This AO is aligned with Republic Act No. 11032, "*Ease of Doing Business and Efficient Government Service Delivery Act of 2018*" that mandated all government offices to adopt simplified requirements and procedures that will reduce red tape and expedite business and nonbusiness transactions in the government. Accordingly, the FDA has done the following measures to ease regulatory burden and expand its customer service:

A. Streamlined the process and simplified the licensing requirements to expedite the processing of applications
B. Removed the requirement of Qualified Person in Industry Regulatory Affairs (QPIRA) certificates to transact business with FDA, or as a condition/requirement to approve LTOs and other authorizations.
C. Launched the FDA eServices Portal
D. Reviewed and updated its Citizen's Charter
E. Established the Food and Drug Action Center to cater to stakeholder's inquiries and complaints
F. Continuous conduct of webinars by the FDA Academy and provision of pre-recorded Licensing webinars via the DOH e-Learning Platform
G. Provision of Information Education and Communication (IEC) materials such as video tutorials, brochures and leaflets, infographics, social media cards, and Frequently Asked Questions (FAQs), among others

Further, we would like to reiterate Section IV Item 4 of **DOH AO No. 2020-0017 which states that:**

> *"**Qualified Person** refers to an **organic or full-time employee of the establishment** who possess technical competence related to the establishment's activities and health products by virtue of his profession, training or experience. A Qualified Person has the responsibility to comply with the technical requirements of the FDA or discuss or clarify matters with the FDA when submitting technical requirements or engage the FDA officials when conducting inspection or post-market surveillance activities. The qualified person may also be the duly Authorized Person of the establishment."*

Likewise under Section VI .2.A.1 of the same policy provides that:

> *"**Online transactions shall not be entrusted to a person who is not the duly authorized person** since valid applications should be owned by the licensed establishments or the owner/President /CEO. **For emphasis, consultants, liaison officers, or freelancers doing business with the FDA or work on a per product registration/notification basis shall not be considered as duly Authorized/Qualified Persons"**.*

The regulatory requirements and procedures in securing FDA authorizations have been simplified and streamlined **to ease regulatory burden and promote self-reliant business operators.** The FDA recommends that all health product establishments and business operators do their own research and due diligence before engaging with any consultant or consultancy firm and verify any claim made by such individuals or firms.

The FDA encourages the concerned stakeholders to report any suspicious or fraudulent activities related to FDA regulations or approval. For any assistance, inquiries and other concerns, please contact the FDA via **info@fda.gov.ph**. Rest assured that the agency is dedicated to provide better service to its stakeholders.

For information and guidance.

DR. SAMUEL A. ZACATE
Director General