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FDA/BDIP/PAT/NPT/23/0006

21st March 2023

To: Manufacturers and Importers of FDA Regulated Products

Dear Sir/Madam,

COMMUNICATION OF UPDATED GUIDANCE
PROPER PLATFORM FOR ELECTRONIC REGULATORY COMPLIANCE - PHASE/LEVEL 2

This is a follow up to the Food and Drugs Authority's (FDA) letter dated 28 November, 2022 on the above-mentioned subject, which invited market authorisation holders, manufacturers importers and exporters, of its regulated products to register on the ProPerSeals Platform using the link https://bit.ly/ProPerRegister.

In line with this earlier directive of November 2022, several companies with valid registration/market authorisation for FDA regulated products ("registrant entities") have already registered on the properseals.org platform using the entity link: **https://properseals.org/accounts/register/brand_owner/**
Market Authorisation Holders, manufacturers, importers and exporters who are yet to register are required to do so by April 30, 2023.

At this stage, the FDA is moving to Level 2 of the ProPer protocol and phase two of the implementation process. For Level 2 compliance and beyond, Market Authorisation Holders, and other FDA clients authorised to use the Properseals.org platform are expected to use the platform to operate as an electronic register of all products authorised for sale in Ghana pursuant to Part 7 Section 128 of Act 851.

The ProPer platform shall complement the FDA's digital initiatives to create conditions for the total digitalisation of its services, including licensing, registration, inspections, advertising approvals, intelligence gathering and data analysis for monitoring substandard and falsified medical products. The platform shall also be the medium to apply for permits for port clearance subject to ongoing integrations with the ICUMS platform. **Starting May 31st 2023 all permit applications will be issued based on a Level 2 code generated on the ProPerSeals Platform. FDA reserves the right not to issue permits for applications that are not covered by the level 2 code. All FDA clients are therefore urged to comply with this guidance.**

As a regional platform, the FDA expects the ProPer solution to enhance the protection of public health and safety in Ghana, whilst enabling regulatory harmonisation and coordination across Africa to the benefit of industry.

Additional manuals and training sessions (including guidance videos) have been scheduled for all members of the relevant industries. All enquiries regarding registration on the platform and related issues should be directed to Ms. Evelyn Mawuko Ohene at businesspartnerships@fda.gov.gh and copy the technical team at seals@propers.org, tony@propers.org and dennis@propers.org.

Please treat as urgent and comply by April 30, 2023.

Yours faithfully,

DR. DELESE A. A. DARKO
CHIEF EXECUTIVE OFFICER

FOOD & DRUG AUTHORITY