EFDA
የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን
ETHIOPIAN FOOD & DRUG AUTHORITY

ቁጥር / ዋን: 02/6/17/02 DATE / REF.NO: 31 JAN 2024

To: All local manufacturers and importers of Medical Gases

Addis Ababa

Subject: Notification to submit application dossier for Registration and Marketing Authorization of Medical gases

According to Food and Medicine Administration Proclamation 1112/2019 (Article 20 (1)) any medicine shall not be manufactured, imported, exported, stored, distributed, transported, sold, hold or used without Marketing Authorization. Hence, as part of Medicine, Registration and Marketing Authorization (MA) of Medical Gases is crucial to ensure safety, efficacy and quality of Medical Gases.

As you are aware, EFDA has been issuing a pre-import permit for the importation and distribution of Medical Gases. The authority has now developed and published guidelines for the registration of Medical Gases.

Therefore, you are required to compile available information and submit your application for registration and marketing authorization of your product(s) as per the approved guidelines.

With regards

Seble Shambel
Lead Executive Officer,
Medicine Evaluation and
Market Authorization

CC

- Director General
- Deputy Director General, Medicine sector
- Lead executive office, Medicine Manufacturers Inspection and Law Enforcement
- Lead Executive office, Pharmacovigilance and Clinical Trial
- Lead executive office, Medicine Quality Control

Ethiopian Food and Drug Authority (EFDA)

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