



RWANDA FDA
Rwanda Food and Drugs Authority

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Re: Circular on Labelling Requirements for Hand sanitizers.

With reference made to the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA, especially in article 8, paragraph 2, the Authority is mandated to regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of products regulated under this law including processed food;

As required by the Guidelines on Submission of Documentation for Registration of Human Pharmaceutical Products, especially in its annex V, whereby the format and content of labels for pharmaceutical products is described, the labelling of the formulated solutions should include at least these requirements:

- a. Proprietary name
- b. Brand name (Hand rub formulation or Hand sanitizer)
- c. Indication of the product
- d. Batch number assigned by the manufacturer
- e. Manufacturing date
- f. Expiry date
- g. Name and address of Manufacturing facility/Compounding Pharmacy
- h. Directions for use, "For external use only"
- i. Warnings or precautions that may be necessary
- j. Avoid contact with eyes
- k. Keep out of the reach of children
- l. A list and concentration of active ingredients: like *alcohol at 70% v/v*, and other ingredients such as Hydrogen peroxide, glycerol or Glycerin
- m. Pharmaceutical form: gel or solution
- n. Storage conditions

Note: The language of the labelling must be presented in at least one of officially recognized languages in Republic of Rwanda.

The Authority is grateful for your collaboration as we strive to prevent the spreading of Coronavirus (COVID-19).

Dr. Charles KARANGWA
Ag. Director General

