ARRANGEMENT OF DOCUMENTS REQUIRED TO APPLY FOR REGISTRATION OF MEDICATED COSMETICS

This arrangement is subdivided in three different parts such as: administrative requirement, raw materials technical data requirements and finished product technical data requirements accordingto the requirements state in these guidelines:

a) The application and supporting document should be submitted in CD-ROM or Externaldriver addressed to Rwanda FDA

b) The application form should be typed in English. Any document which is in any languageother than English must be accompanied by a certified or notarized English translation.

c) Application Form and part three should be in both PDF and word format

d) The PDF documents should be selectable and searchable

e) All pages of the application should be numbered in the style: ***page x of y***.

Therefore, the applicant shall prepare and present the product dossier information in the following format

PART I: ADMINISTRATIVE REQUIREMENT

1.1 Table of content

1.2 Dated and signed cover letter

1.3 Completed application form (dated, signed and stamped)

1.4 Manufacturing sites and responsibility

1.5 Contract Manufacturing Agreement (where applicable)

1.6 A valid marketing authorization certificate

1.7 A valid manufacturing license.

1.8 A valid GMP Certificate (ISO 22716 Cosmetic GMP Certifications) or other applicableinternationally recognized Management System certification

1.9 Two commercial samples

1.10 Two (2) colored Label of the product

1.11 Leaflet insert of the product (where applicable)

1.12 Appointment letter of the local technical representative with original copy of Powerof attorney from the product manufacturer

1.13 Two CD- Rom or external driver virus free containing all information

1.14 Proof of payment of non-refundable registration application fee

PART II: RAW MATERIALS TECHNICAL DATA REQUIREMENTS

2.1 Table of content

2.2 INCI Name for each ingredients

2.3 CAS (Chemical Abstract Service) number of ingredients

2.4 Name and address of manufacturer for each ingredients

2.5 Certificate of Analysis(COA) for each ingredient

2.6 Specifications of raw materials

2.7 Storage conditions and shelf life for each ingredients

2.8 Active ingredient(s) stability studies

2.9 Material Safety Data Sheets (MSDS) for each ingredient

PART III: FINISHED PRODUCT TECHNICAL DATA REQUIREMENTS

3.1 Table of content

3.2 Description of finished product and its intended use

3.3 Data Composition (ingredients, quantity, role) of product in tabular format.

3.4 Manufacturing process

3.5 Method of analysis and specification of the finished product

3.6 Packaging and labelling information

3.7 Stability data

3.7.1 Study design (protocol)

3.7.2 Test conditions, testing interval and Duration, Type of container used and Parameters to betested

3.7.3 Test results

3.8 Material Safety Data Sheets of finished product (MSDSFP)