MINISTRY OF HEALTH & WELLNESS

STANDARDS & REGULATION DIVISION
Website: www.moh.gov.jm
JAMAICA, WEST INDIES

REGISTRATION OF MEDICAL DEVICES
FOOD AND DRUGS ACT 1964

Product Particulars:

1. NAME OF DEVICE

……..……..

2. NON-PROPRIETARY DESIGNATION OF DEVICE:

……

3. NAME AND ADDRESS OF MANUFACTURER:……..……

……

4. NAME AND ADDRESS OF APPLICANT:…….

……

5. NAME & ADDRESS OF LOCAL REPRESENTATIVE (If different from above): -

……

LIST OF REQUIREMENTS FOR ASSESSMENT PURPOSES:

1. Three copies of a summarized statement (not package insert) giving information on the following where applicable:
    a. All ingredients present in the device and their concentration
    b. Instructions for use
    c. Therapeutic/diagnostic claims/intended use
    d. Patient population for which the device is intended
    e. Description of the device, including components
    f. Functioning principle (diagrammatic representation of the mechanism of action)
    g. Physical and performance characteristics (device design, material used and physical properties)

h. Contraindications/precautions;
i. Adverse effects and complications

j. Toxic effects and protocol for treating toxicity
k. Performance tests

2. Details of the tests conducted to control the potency, purity, and stability. Stability data with shelf life conclusion will be required.

3. Summary of:

   a. Effectiveness: controlled studies; uncontrolled studies;

   b. Safety: adverse reactions in volunteers and where the device has been marketed for less than five (5) years, adverse reactions in patients.

4. A Certificate of Analysis (original, not photocopy) or a certified report containing: -
   a. Assay report on a recent batch of the product analyzed; including specifications.
   b. Two (2) copies of the method of analysis used.

5. Three (3) copies of a draft of every label bearing the name and address of the manufacturer proposed to be used in connection with the product, a batch/lot number, date of manufacture, storage conditions (including temperature) and expiry date of the product.

6. Three (3) samples of the device in the finished form in which it is to be sold and/or biological reference standards of active ingredients necessary to perform analyses described in four (b).

7. Manufacturing processes and the quality assurance programme designed to assure and verify the quality of the process used to manufacture the device. This should include the methods used in and controls used for the design, manufacture, packaging, labelling and storage of the device.

8. A "Certificate of Good Manufacturing Practice" providing information on the facilities and operations as recommended by the World Health Organization.

9. The Premarket Approval (original, not photocopy) bearing information as recommended by World Health Organization from the competent health authority in the country of manufacturer certifying that the device is approved for use in that country and the conditions under which it may be sold in that country.

10. Package insert for physicians which provides information on the risks of the device, instructions for use and age indication.

11. Information brochure for patients which includes short-term as well as long-term risks.

12. A statement showing:

    a. The countries in which the product is approved for sale other than the country in which it is manufactured.

    b. Any country in which use of the product has been refused and the reasons for refusal.

13. Any other relevant information.

14. Official documents such as provided by the competent authority in the country of origin should be authenticated by the Jamaican Embassy or Jamaican Consulate in the country.

15. The document submitted **must** be in the English Language or authenticated translation, should be bound in a hard cover and correctly indexed in the order presented above for easy reference.

16. The registration fee for each presentation is five thousand dollars (J$5,000.00). Cheques **must** be made payable to the Permanent Secretary, Ministry of Health.

17. **All the above requirements must be submitted at the same time to the Pharmaceutical & Regulatory Affairs Department, Standards & Regulation Division. Incomplete submissions will not be accepted**

    NB.

    Acceptance of documents for registration is not an automatic indication by the Ministry of Health that the product will be registered.

    Products submitted for registration should be on the market in the country of manufacture or export for at least one (1) year prior to submission.

Conditions of Registration:

List 4	Prescription Only
List 2	Over-the-Counter, Pharmacy only.
List 1	Over-the-Counter, not limited to Pharmacies

FOR OFFICE USE ONLY

DATE RECEIVED:……..
NOTIFICATION SENT:…….
ASSESSMENT COMMENTS:……
DATE APPROVED/REFUSED:……

M.H.F.D. 13 Revised July 2021