MINISTRY OF HEALTH
STANDARDS & REGULATION DIVISION
PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT
JAMAICA, WEST INDIES
REGISTRATION OF NEW DRUGS
FOOD AND DRUGS ACT 1964

Product Particulars:

1. NAME OF DRUG:
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2. GENERIC NAME OR NON-PROPRIETARY DESIGNATION OF DRUG:

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

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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 the information on:

    a. All ingredients present in the formulation;
    b. Dose, Dose Schedule, Route of administration;
    c. Therapeutic/diagnostic claims;
    d. Description of dosage form being registered;
    e. Contraindication/precautions;
    f. Side effects;
    g. Toxic effects, and protocol for treating toxicity or where applicable, antidote.

2. Details of the tests conducted to control the potency, purity, and stability.

3. Summary of:
    a. Clinical Pharmacology: pharmacodynamics; pharmacokinetics;

bioavailability;. Bioequivalence studies including not less than twelve (12) subjects for all generic preparations.

b. Efficacy: controlled studies; uncontrolled studies;

c. Safety: adverse drug reactions in volunteers and where a new chemical moiety has been marketed for less than five (5) years, adverse drug 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 analysed;
   b. The method of analysis used.

5. Five (5) copies of a draft of every label bearing the address of the **manufacturer** proposed to be used in connection with the product, a batch/lot number and expiry date of the product.

6. Five (5) samples of the new drug in the finished pharmaceutical form in which it is to be sold along with adequate amounts of appropriate chemical and/ or biological reference standards of active ingredients necessary to perform analysises described in three (b).

7. A "**Certificate of a Pharmaceutical Product**" (original, not photocopy) bearing information as recommended by W.H.O. from the competent health authority in the country of manufacturer certifying that the drug is approved for use and registered in that country and the conditions under which it may be sold in that country.

8. 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 the product has been refused registration and the reasons for refusal.

9. Any other relevant information.

10. Official documents such as the Certificates of Pharmaceutical Product should be authenticated by the Jamaican Embassy or Jamaican Consulate in the country, and in cases where none of these is present by the British High Commission or British Embassy.

11. The document submitted **must** be in the English Language or authenticated translation should be bound in a hard cover with dimensions of approximately
    9" x 11 ½ " and correctly indexed in the order presented above for easy reference.

12. 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.

13. All the above requirements must be submitted at the same time to the **PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT. Incomplete submissions will be returned to the applicant.**

Note: GENERIC COMPANIES ARE REQUIRED TO INDICATE THE EXPIRY DATE OF THE PATENT ON THE PRODUCT BEING SUBMITTED FOR REGISTRATION.

ACCEPTANCE OF REGISTRATION DOCUMENTS BY THE MINISTRY OF HEALTH IS NOT AN INDICATION THAT REGISTRATION IS AUTOMATIC.

WITH THE EXCEPTION OF PRODUCTS INDICATED FOR LIFE THREATENING ILLNESSES (e.g. HIV, CANCER), 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.

FOR CONSIDERATION OF APPROVAL IN JAMAICA WHERE AN INNOVATOR DRUG IS NOT REGISTERED IN JAMAICA ANY GENERIC FORM SUBMITTED FOR APPROVAL WILL BE CONSIDERED A NEW DRUG. THE LIST OF REQUIREMENTS FOR A NEW DRUG WILL THEREFORE APPLY.

CONDITIONS OF REGISTRATION: -

LIST 4	**Prescription Only**
LIST 2	**Over-the-Counter LIST 2 Drug by the Pharmacy Council of Jamaica and may be sold in Pharmacies ONLY**
LIST 1	**Over-the-Counter LIST 1 Drug by the Pharmacy Council of Jamaica and may be sold in shops other than Pharmacies**

FOR OFFICE USE ONLY

DATE RECEIVED:……..

NOTIFICATION SENT:…….

ASSESSMENT COMMENTS:……

DATE APPROVED/REFUSED:……

M.H.F.D. 13 Revised May 2006.