MINISTRY OF HEALTH
STANDARDS & REGULATION BRANCH
PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT
JAMAICA, WEST INDIES

REGISTRATION OF HERBAL PRODUCTS
FOOD AND DRUGS ACT 1964

PRODUCT PARTICULARS:

1. NAME OF PRODUCT:

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2. GENERIC NAME OR NON-PROPRIETARY DESIGNATION OF PRODUCT:

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3. NAME & ADDRESS OF MANUFACTURER: .....

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4. NAME &ADDRESS OF APPLICANT: .....

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LIST OF REQUIREMENTS FOR ASSESSMENT PURPOSES:

1. Three copies of a summarised 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;

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

3. A Certificate of Analysis (original, not photocopy) containing:-

   a. Assay report on a recent batch of the product analysed;
   b. The method of analysis used.

4. 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.

5. Five (5) samples of the product in the finished 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 analyses described in two (2).

6. A **"CERTIFICATE OF FREE SALE"** (original, not photocopy)

7. A statement showing:

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

   a. Any country in which the product has been refused registration and the reasons for refusal.

8. Any other relevant information.

9. Official documents such as Certificates of Free Sale should be authenticated by the Jamaican Embassy or Jamaica Consulate in that country, and in cases where none of these is present by the British High Commission or British Embassy.

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

11. 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.

12. All the above requirements must be submitted at the same time to the **PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT**.

N.B. ACCEPTANCE OF REGISTRATION DOCUMENTS BY THE PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT IS NOT AN INDICATION THAT REGISTRATION IS AUTOMATIC.

FOR OFFICE USE ONLY

DATE RECEIVED: .....

NOTIFICATION SENT: .....

ASSESSMENT COMMENTS: .....

DATE APPROVED/REFUSED: .....