*(Legislative Supplement No. 17)*

LEGAL NOTICE No. 142

THE PHARMACY AND POISONS ACT

(*Cap.* 244)

IN EXERCISE of the powers conferred by section 44 of the Pharmacy and Poisons Act, the Minister for Health, after consultation with the Board, makes the following Rules:—

THE PHARMACY AND POISONS (REGISTRATION OF DRUGS) (AMENDMENT) RULES, 1991

1. These Rules may be cited as the Pharmacy and Poisons (Registration of Drugs) (Amendment) Rules, 1991.

2. Rule 4 of the Registration of Drugs Rules is amended— Sub. Leg.

(*a*) by inserting the following sub-rule (3) immediately after sub-rule (2)—

(3) An application for renewal of registration of a drug under rule 7, shall be in Form 1A set out in the Schedule; and

(*b*) by inserting Form 1A set out in the Schedule immediately after Form 1 as follows—

SCHEDULE

*CONFIDENTIAL* FORM 1A

THE PHARMACY AND POISONS ACT

(*Cap.* 244)

APPLICATION FOR RE-REGISTRATION OF A DRUG

(*to be submitted in sextriplicate*)

The Registrar
Pharmacy and Poisons Board
P.O. Box 30016
Nairobi

1. Name of Applicant (manufacturer) .....
Registered physical business address
(*See note* (1) .....
.....
.....
Telephone No. (Office) .....
2. Name of product to be re-registered .....
.....
Type of formulation (*see note* 2) .....
.....
Presentation of the product .....

SCHEDULE—(*Contd.*)

3. Identification physical appearance of the product) .....

.....

4. (*a*) Therapeutic classification(s) .....

.....

.....

(*b*) Specific indication(s) .....

.....

.....

(*c*) Category (*see note* 3) .....

.....

.....

5. Name and business address of manufacturer .....

.....

.....

.....

6. Registration number of the product in Kenya .....

.....

Date of first registration .....

7. Has the product been discontinued in any country? .....

.....

If yes, why? .....

.....

.....

8. Have you changed the pharmaceutical formula? .....

If yes, state changes and provide the new formula .....

.....

.....

9. Have you changed the manufacturing procedures? .....

If yes, state the new changes .....

.....

10. Have you made any other changes in quality control of finished products, analytical procedures and packaging specifications? .....

If yes, state new specifications .....

.....

SCHEDULE—(*Contd.*)

11. Provide recent (5-10 years) pharmacological, physiological, clinical, toxilocological and bioavailability data (*see note* 4) .....

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12. We the undersigned hereby declare that all the information contained herein is correct to the best of our knowledge:

| | *Name* | *Signature* | *Qualifications* | *date* |
|---|---|---|---|---|
| (*a*) Quality Control Manager | ..... | ..... | ..... | ..... |
| (*b*) Production Manager | ..... | ..... | ..... | ..... |
| (*c*) Registration Officer (*see note 5*) | ..... | ..... | ..... | ..... |

*Notes*—

(1) for foreign manufacturers give your local agents contacts;

(2) tablet, capsule injections;

(3) prescription only medicine (POM), over the counter medicine (OTC), pharmacy medicine (P), general sales (GS);

(4) for veterinary products, provide residue levels in milk and meat;

(5) for (*c*) local manufacturers, local agents—the company pharmacist is to sign.

(6) a separate application is required for each drug;

(7) reapplication fee is not refundable;

(8) a dosage form in a specific strength shall be considered as a drug;

(9) applicants are notified that any false information given in the application may lead to fines and refusal of subsequent registration of products;

(10) each reapplication must be accompanied by six samples of the smallest commercial pack.

*Date* ..... .....

*Signature of Applicant*

Made on the 28th March, 1991.

MWAI KIBAKI,
*Minister for Health.*