National Agency for Food & Drug Administration & Control (NAFDAC)

Drug Registration & Regulatory Affairs (DR & R) Directorate

LABEL GUIDANCE FOR HERBAL MEDICINES AND DIETARY SUPPLEMENTS

1.0. OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATEPACKAGING

The minimum labelling requirements are:

1.1. The Brand name of the product, strength (amount of each active ingredient present in a dosage unit or percentage) and dosage form.
1.2. NAFDAC Disclaimer: These claims have not been evaluated by NAFDAC. (Not for Dietary Supplements).
1.3. Caution: Not to be taken by Pregnant women, Nursing mothers and children below twelve (12) years old. (Not for dietary Supplements).
1.4. The name and address of the supplier manufacturer. The details of the applicant if different fromthe manufacturer can be stated.
1.5. The batch information (i.e. batch number, manufacturing and expiry dates) assigned by themanufacturer.
1.6. NAFDAC Registration Number.
1.7. Special warning that the medicinal product must be stored out of the reach and sight of children("Keep out of the reach and sight of children").
1.8. Special storage conditions.
1.9. No pictorial (For Herbal medicines).
1.10. Product indication.
1.11. Dosage administration and/or Direction for use where applicable.

2.0. LEAFLET INSERT

The leaflet should contain the following information:

1. BRAND NAME
2. Active ingredients quantitatively (dosage unit or percentage).
3. Indication.
4. NAFDAC Disclaimer: These claims have not been evaluated by NAFDAC.
5. Caution: Not to be taken by pregnant women, nursing mothers and children.
6. Dosage administration and/or Direction for use where applicable.
7. Special warning that the medicinal product must be stored out of the reach and sight of children("Keep out of the reach and sight of children").
8. The name and address of the supplier manufacturer. The details of the applicant if different fromthe manufacturer can be stated.

3.0. FOR BLISTERS AND STRIPS

Blisters and strips should include, as a minimum, the following information:

1. Name, strength, and pharmaceutical form of the Finished product.
2. Name of the supplier (i.e., the manufacturer)
3. Manufacturing date in un-coded form.
4. Expiry date in an un-coded form. [Note that for co-blistered products, the expiry date is that of the product which expires first.]
5. Batch number assigned by the manufacturer
6. Directions for use, and any warnings or precautions that may be necessary.