DOCUMENT TITLE: REGULATORY DIRECTIVE ON DISCONTINUED REGISTRATION OF MULTI-DOSE ANTI-MALARIA ORAL SUSPENSIONS		
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NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Regulatory Directive on Discontinued Registration of Multi-Dose Anti-Malarial Oral Ssuspensions.

1.0. Purpose:

This regulatory directive stipulates the discontinued registration of Multi-Dose Anti-Malaria Oral Suspensions in the treatment of malaria due to instability of the reconstituted formulations. Stability studies have shown that reconstituted antimalarial suspensions are unstable and so loses its efficacy.

2.0. Scope:

This Regulatory Directive applies to local and imported Multi-Dose Anti-malarial Oral Suspensions for New, Renewal & Variation applications.

3.0. Directive Details:

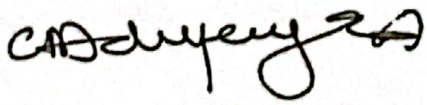
NAFDAC no longer accepts New, Renewal or Variation applications of the locally manufactured and imported Multi-Dose Anti-malarial Oral Suspensions.

Granules of Multi-Dose Anti-malarial Oral Suspensions in single dose sachets or already-registered products re-formulated to dispersible tablets will be accepted by the Agency for Locally manufactured and Imported new, renewal and variation applications.

Approved by:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature:  **Date:** 1/7/2024

Legend:
RDXX
RD: Regulatory Directive
XX: First two letters of the first two words of the document title.