All correspondence should be addressed to the Director General

DMS/7/9/22/PR/266

In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

24th June, 2016

Pharmanova (Zambia) Limited
P.O.Box 35722, 7329 Moobola Road
Lusaka
Zambia

Dear Sir/Madam,

RE: APPLICATION FOR AMENDMENT TO MARKETING AUTHORISATIONS

Reference is made to your application for amendment of marketing authorization of a pharmaceutical product, submitted in line with Section 39 of the Medicines and Allied Substances Act (No. 3) of 2013

Name of product	Marketing Authorisation number	Details of amendment:
Kit Yamoyo "Essential" Orange Flavour without soap containing Low Osmolality Oral Rehydration Salts BP ORS Novalyte 4.12g	077/026	Removal of soap in the kit and addition of "Essential" highlighted in green colour background on the leaflet of the additional pack for ease of identification and differentiate from the regular approved pack that has soap

We wish to advise that we have completed our review of the above mentioned application. Approval of the amendment/variation has been granted and our records have been updated.

We also wish to advise that, with effect from 1st January 2016, the Authority implemented the use of the Common Technical Document (CTD) as a format for submission of applications for marketing authorisation of medicines for human use. Applications that are not in CTD format will not be accepted. Please refer to the CTD guidelines at http://www.zamra.co.zm/guidelines.

Should you have any questions, please do not hesitate to contact our Secretariat.

Yours faithfully,
Zambia Medicines Regulatory Authority

Z. Munkombwe (Dr)
DIRECTOR MEDICINES CONTROL
For/DIRECTOR GENERAL

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Report Adverse Reactions to:
Pharmacovigilance Unit, Lusaka
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E-mail:pharmacy@zamra.co.zm