

Food and Drugs Authority

Head Office P. O. Box CT 2783, Cantonments, Accra-Ghana Tel: (+233-302)233200, 235100

Fax: (+233-302)229794, 225502 Email: fda@fdaghana.gov.gh

15th November 2016

FDA/MCH/CHC/HCS/16/1190

The Director Cramer Lycatrol Resources Ltd P.O.Box CT 11130 Accra Tel: 0266021776

Dear Sir/Madam,

REGISTRATION OF HOUSEHOLD CHEMICAL SUBSTANCE

This is to inform you that the Food and Drugs Authority (FDA) has completed the review of your household chemical substance application submitted pursuant to Section 118 of the Public Health Act, 2012 (Act 851) for the registration of **ONE DROP WATER**

Based upon the information presented to date, the FDA has concluded that the household chemical substance is safe for use as recommended in the submitted labelling, subject to the conditions in this letter.

Your application has therefore been approved and issued with the registration number FDB/C.16-11140

This registration is valid for three (3) years and expires on December 1, 2019.

A certificate of registration is being processed for collection in room 307 of the FDA's Head Office.

The conditions which apply are as follows:

- The household chemical substance must conform to all the details submitted in your application and as modified in subsequent correspondence.
- The product cannot be advertised via promotional material/product launch unless the advertisement has been vetted and approved by the FDA.
- No changes may be made to the indications, quality specifications, composition and packaging materials of the household chemical substance without prior approval from the FDA.
- Importation of the product is not permitted after the period of validity of the registration has expired.

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Post Marketing Surveillance activities into the quality of the product are ongoing and any adverse findings will be brought to your immediate attention and the necessary regulatory measures taken.

Please ensure that you promptly communicate any change in the safety information on the product to the FDA.

Yours faithfully,

HUDU MOGTARI

CHIEF EXECUTIVE OFFICER

cc: HN20 (PTY) Ltd, Unit 20 Boulevade Business Park, Belladonna Road Cornubia Durban 4345, South Africa.

All FDA Regional Offices