



RWANDA FDA

Rwanda Food and Drugs Authority

P.O. Box 84 Kigali

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Kigali on,

Ref N°:DIS/

/FDA/2021

A.K. Gupta

Technical Director

Blue Cross Laboratories Pvt Ltd

Tel: 022-6663 8000

Mumbai, INDIA

Dear Sir/Madam,

Re: Response to your letter alerting on presence of counterfeit product on Rwanda Market-MEFTAL FORTE + CREAM

Reference made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority, especially in its article 8, paragraph 9, the Authority is mandated to conduct pharmacovigilance and post marketing surveillance for safety and quality of regulated products among other regulatory functions;

Further reference is also made to the letter dated 22nd October 2020 confirming the presence of counterfeit MEFTAL Forte Cream on Rwanda Market; and considering the findings of investigation through Post Marketing Surveillance activities conducted by Rwanda FDA which revealed reported medicines with the described characteristics were imported in the country.

Following our e-mail dated 18th December 2020 requesting some clarifications and taking into consideration your response letter dated 21st December 2020 confirming that the suspected batch

was manufactured by BLUE CROSS LABORATORIES PVT Ltd at your Goa Plant; we would like to bring to your attention that Meftal forte cream was officially imported by a wholesaler recognized by Rwanda FDA from a distributor in India called Dheer Health Care Private Limited in Mumbai, India. Therefore, you are advised to enhance control of distributors of your products

As your company submitted the application for the product registration this will prevent the re-occurrence of this incident and the Authority is requesting your company to submit the list of all authorized distributors in Rwanda for import control.

Thank you for your usual collaboration

Dr. Charles KARANGWA
Ag. Director General