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THE STATE OF ERITREA
MINISTRY OF HEALTH
NATIONAL MEDICINES AND FOOD ADMINISTRATION

دولة ارتريا
وزارة الصحة

Date: 2022-05-09
Ref: [NMFA/XX/YEAR/Sequential Number]
To:
street/plot number:
region/state:
country:
Subject: Decision on registration application for
Dear ,
As per your application for (re-)registration of dated [date/month/year] , has been completed through the [registration procedure/route]. The National Medicines and Food Administration (NMFA), at its discretion, has granted **approval** of the registration application subject to the conditions of this letter. This letter and the attached Certificate of Registration constitute the approval. Due to the below mentioned reasons, the NMFA, at its discretion, has decided to defer the registration application.

The conditions that apply are as follows:

- The medical product should conform to all the details provided in your applicationand dossier and as modified in subsequent correspondences.
- The medical product should be dispensed as *[Schedule of the medical product]*.
- No changes should be made to the quality specification, composition, packaging material, manufacturing process and site of manufacture without prior approval from the NMFA.
- You are obliged to monitor the quality of the product on the market and report quality defects to the NMFA for the appropriate regulatory action to be taken.
- You are obliged to monitor the safety of the product granted marketing approval and report all adverse reactions or events to the NMFA.
- You are requested to promptly communicate any changes in the safety information on the Finished Pharmaceutical Product (FPP) to the NMFA.
- The manufacture and control of medicines should be in accordance with the current Good Manufacturing Practices (cGMP).
- In order to assess compliance with GMP requirements, inspections and investigations may be carried out regularly by authorized inspectors, as deemed necessary.
- The medical product should be imported in compliance to the provision of the Proclamation no. 36/1993.
- You should ensure that the Marketing Authorization (MA) is not transferred without written approval of the NMFA.
- You are obliged to notify the NMFA of any changes or amendments (variations) that may affect the quality, safety and efficacy of the FPP.
- You are obliged to renew the registration application in due time (not later than three months prior to the expiry date of the registration).

Best regards,

Iyassu Bahta
Director, National Medicines and Food Administration
Ministry of Health
Asmara, Eritrea

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MFA
ERITREA
NATIONAL MEDICINES AND FOOD ADMINISTRATION

تلفون ٢٩١-١-١٢٥٥٢٥
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فاكس ٢٩١-١-١٢٢٨٩٩
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