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कार्यालय
केयमि निवेदनक (सब.) जयपुर
06 FEB 2014
1320

File No. 6-3/ BD/206/03- DC (Re- Registration 2013)
DIRECTORATE GENERAL OF HEALTH SERVICES
OFFICE OF DRUG CONTROLLER GENERAL (INDIA)
(IMPORT & REGISTRATION DIVISION)

FDA Bhavan, Kotla Road
New Delhi 110 002

Date: 28/01/2014

To,
All State Drugs Controllers

Sub: Drug alert - Tiamulin Hydrogen Fumarate (80% granules) Imported by
M/s. Novartis India Limited, Mumbai - reg.

Sir,

This is to inform you that M/s. Novartis India Limited, Animal Health Business Unit, Sandoz House, Shivsagar Estate, Dr. Annie Beasant Road, Worli, Mumbai - 400018 had submitted a Certificate of Suitability (CEP) for Tiamulin Hydrogen Fumarate (80% granules) for Import registration of this drug. On verification about the authenticity of this certificate from European Directorate for the Quality Medicines (EDQM); it was found that the CEP submitted by them is fake.

In view of the same you are hereby requested to alert your inspectorate and to draw samples of the formulations containing the said drug Tiamulin Hydrogen Fumarate and other drugs imported and marketed by M/s. Novartis India Limited, Mumbai.

(Dr. G. N. Singh)

Drugs Controller General (I)

GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAWAN,
TILAK MARG JAIPUR

No.DC/D-1/General File/2014/ 103

Dated:- 14.02.2014

Copy forwarded to following for necessary action:-

- 1- All Drugs Control Officer, Rajasthan State.
- 2- Incharge Server Room Hqrs; with requested to upload this letter on department website & E-mail this letter to all Asstt. Drugs Controller, Rajasthan State.

(Ashok Bhandari)
Drugs Controller
Rajasthan Jaipur