

From:
The Drugs Controller General (India)
Directorate General of Health Services

FDA Bhawan, New Delhi
Dated

To,

06 JUL 2015

M/S. B.M Chemie,
Bldg. No.B, Gala No.110, 1st Floor,
Shree Sambhav Complex,
Rehnal Village, Bhiwandi, District-Thane
Maharashtra

Sub: -Registration of M/S. Henan Lihua Pharmaceutical Co. Ltd. Middle Of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan, China under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

Please refer to your application No. NH dated 24.04.2015 received by this Office vide diary No. 13636 dated 29.04.2015 on the above subject. Registration Certificate in Form 41 under the Rules is issued on the manufacturing site along with the name (s) of drug (s) imported under the said Certificate subject to the condition:

1. The drugs shall conform to the standards / specifications mentioned in the Second Schedule of the Act, or such other standards / specifications forwarded by you and approved by this Directorate.
2. The drugs shall have the composition, strengths, standards and packing as approved by this Directorate.
3. Dispute, if any, in respect of the payment of fees and submission of TR6 challan shall have to be settled between the bank and the applicant.
4. The drugs will be required to be withdrawn from sale from the market in case any undesirable reactions due to its medication are brought to light at any stage. This Directorate should be informed of adverse reports on the drug, if any.
5. The drugs shall be marketed for indications for which they have been approved.
6. If any claim is made for these drugs in future other than those approved, prior permissions from this Directorate will be necessary before such claim is made.
7. The drugs shall be supplied and marketed as per the provisions of the existing Drugs & Cosmetics Act and Rules thereunder.

FORM 9
VALID ONLY ISSUED BY B.M CHEMIE

GOVERNMENT OF INDIA

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)



सत्यमेव जयते

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED
UNDER REGISTRATION CERTIFICATE NO. RD-917
DATED 06 JUL 2015 VALID UPTO 28/02/2017

ENDORSEMENT No. 1

1. Prednisone IP
2. Hydrocortisone Acetate IP

ITEMS (Two) ONLY

FORM 9 VAILD ONLY ISSUED BY B.M CHEMIE

Place: New Delhi

Date: 06 JUL 2015



LICENSING AUTHORITY

(डॉ. वी. जी. सोमानी / Dr. V. G. Somani)
संयुक्त श्रेयस्मि निदेशक (संयुक्त श्रेयस्मि) Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Directorate General of Health Services
एन.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002
FDA Bhawan, Kotla Road, New Delhi-110002

Seal/Stamp

Vhs

- 8 This registration in no way relieves you of the responsibility of complying with all other provisions of the Drugs & Cosmetics Act and Rules there under, and any other provisions of any other Act and Rules applicable in the matter concerned.
- 9 Each consignment of the drugs to be imported by you shall be accompanied by a test / analysis reports.
- 10 Based on this registration, import applications for the drug (s) endorsed in the enclosed Registration Certificate shall be considered for the issue of Form 10 Licence under the Rules.
- 11 This Registration Certificate is being issued under the condition that during the pendency of Registration, the applicant may be required to deposit inspection fee as stipulated under Clause (5) of Rule 24-A and enable inspection of manufacturing site by the officials authorised for this purpose. Non-compliance to this condition as and when so directed would result in cancellation of Registration Certification.
- 12 The Shelf-life of the drugs Prednisone IP and Hydrocortisone Acetate IP is 36 months each.
- 13 The firm shall submit long term stability data as per Indian climatic condition Zone IVb for the proposed shelflife.

Please note that Registration Certificate issued is liable to be suspended / cancelled, if any of the condition stipulated above is not complied with, apart from any other condition that may be taken under the provisions of the Drugs & Cosmetics Act, 1940 and the Rules there under.

Please acknowledge the receipt.

Yours faithfully,

V. Ch.

Joint Drugs Controller (India)

Copy forwarded to:

1. The Assistant Drug Controller (I), New Custom House, Annexe, Ballard Estate, Fort, Mumbai-400038.
2. The Assistant Drug Controller (I), 15/1, Strand Road, Custom House, Kolkata-700001.
3. The Assistant Drug Controller (I), Room No. 66, 2nd Floor, Custom House, Chennai-600001.
4. The Assistant Drug Controller (I), JawaharlalNehruPort, TrustNhavaSevaPort, Raigard, Maharashtra.
5. The Assistant Drug Controller (I), International Air Cargo Complex, IndiraGandhiInternationalAirPort, New Delhi-110037.