

No. 6-4/FF/11/05-DC(REREG2011)

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

FDA Bhawan, New Delhi

Dated

06 JUN 2011

To,

M/S. WYETH LIMITED
LEVEL 6, PLATINA, PLOT NO. C-59,
'G'BLOCK, BANDRA-KURAL COMPLEX,
BANDRA(EAST)
MUMBAI-400098

Sub: -Registration of M/S. PFIZER BIOTECH CORPORATION, HSINCHU PLANT, NO. 290-1, CHUNG LUN, CHUNG LUN VILLAGE, HSINFENG, HSIN CHU, HSEIN, 304 TAIWAN R.O.C under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

Please refer to your application no. NIL dated 12/05/2011, received by this Office vide diary no. 22572 dated 12/05/2011 on the above subject. Registration Certificate in Form 41 under the Rules is issued for 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 The drugs will be required to be withdrawn from sale from the market in case any undesirable reactions due to its medication are brought to light at any stage.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.

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. **ORIGINAL LABEL OF DRUG ALONG WITH PACKAGE INSERT SHALL BE SUBMITTED TO THIS OFFICE BEFORE IMPORT OF DRUG.**

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,

Drugs Controller General (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), Jawaharlal Nehru Port, Trust Nhava Seva Port, Raigard, Maharashtra.
5. The Assistant Drug Controller (I), International Air Cargo Complex, Indira Gandhi International Air Port, New Delhi-110037.



GOVERNMENT OF INDIA

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

Form 41

(See Rule 27-A)

REGISTRATION CERTIFICATE

Registration Certificate issued for import of drugs into India

Under Drugs and Cosmetics Rules, 1945

Registration Certificate No. FF-331

Dated

06 JUN 2011

1. M/S. PFIZER BIOTECH CORPORATION, HSINCHU PLANT, NO. 290-1, CHUNG LUN VILLAGE, HSINFENG, HSIN CHU, HSEIN, 304 TAIWAN R.O.C having factory premises at M/s. PFIZER BIOTECH CORPORATION, HSINCHU PLANT, NO. 290-1, CHUNG LUN, CHUNG LUN VILLAGE, HSINFENG, HSIN CHU, HSEIN, 304 TAIWAN R.O.C has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.
2. Name(s) of drug(s), which may be imported under this Registration Certificate (Please refer the enclosed list of drugs).
3. This Registration Certificate shall be in force from 01/04/2011 to 31/03/2014 unless it is sooner suspended or cancelled under the rules.
4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/S WYETH LIMITED LEVEL 6, PLATINA, PLOT NO. C-59, 'G'BLOCK, BANDRA-KURAL COMPLEX, BANDRA (EAST) MUMBAI-400098 who will be responsible for the business activities of the manufacturer in India in all respects.
5. This Registration Certificate is subject to the conditions stated overleaf and to such other conditions as may be specified in the Act and the Rules, from time to time.



Place: New Delhi

Date: 06 JUN 2011

LICENSING AUTHORITY

डा. सुरिंदर सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Kolla Road,
New Delhi-110002

Conditions of the Registration Certificate

1. The Registration Certificate shall be displayed at a prominent place by the authorised agent.
2. No drug shall be registered unless it has a free sale approval in the country of origin, and/or in other major countries.
3. The manufacturer or his authorised agent in India shall comply with the conditions of the import licence issued under the Drugs and Cosmetics Rules, 1945.
4. The manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed. The despatch and marketing of the drug in such cases shall be stopped immediately, and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of drug shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned drug in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours time period.
5. The manufacturer or his authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the drug pertaining to this Registration Certificate. In such cases, where there shall be any major change/modification in manufacturing, or in processing or in testing, or in documentation as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub rule (3) of rule 24-A.
6. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and /or address of the registered office/ factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises".



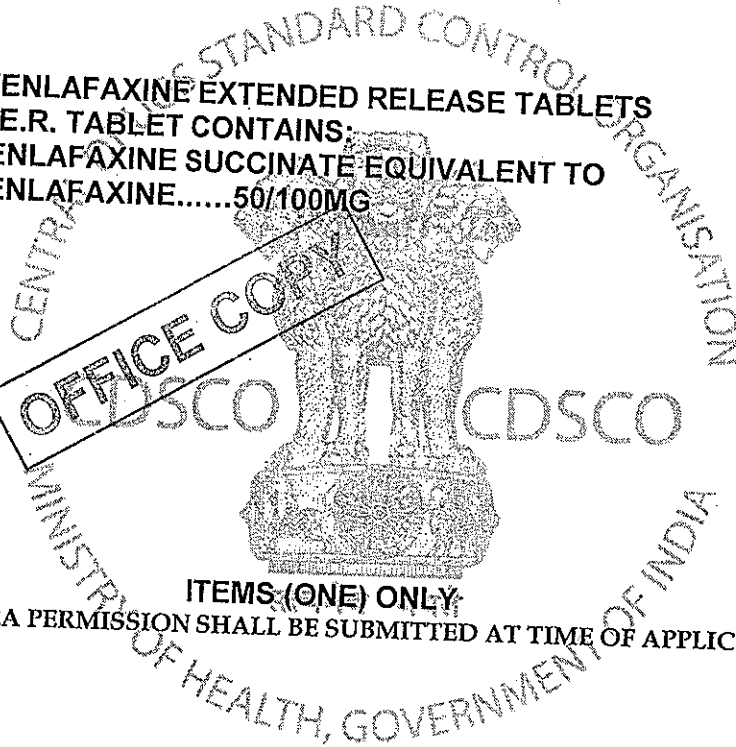
सत्यमेव जयते

GOVERNMENT OF INDIA
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED
UNDER REGISTRATION CERTIFICATE NO. FF-331
DATED 06 JUN 2011

*DESVENLAFAXINE EXTENDED RELEASE TABLETS
EACH E.R. TABLET CONTAINS:
DESVENLAFAXINE SUCCINATE EQUIVALENT TO
DESVENLAFAXINE.....50/100MG



ITEMS (ONE) ONLY:
*COPY OF RULE 122A PERMISSION SHALL BE SUBMITTED AT TIME OF APPLICATION OF
IMPORT LICENSE.

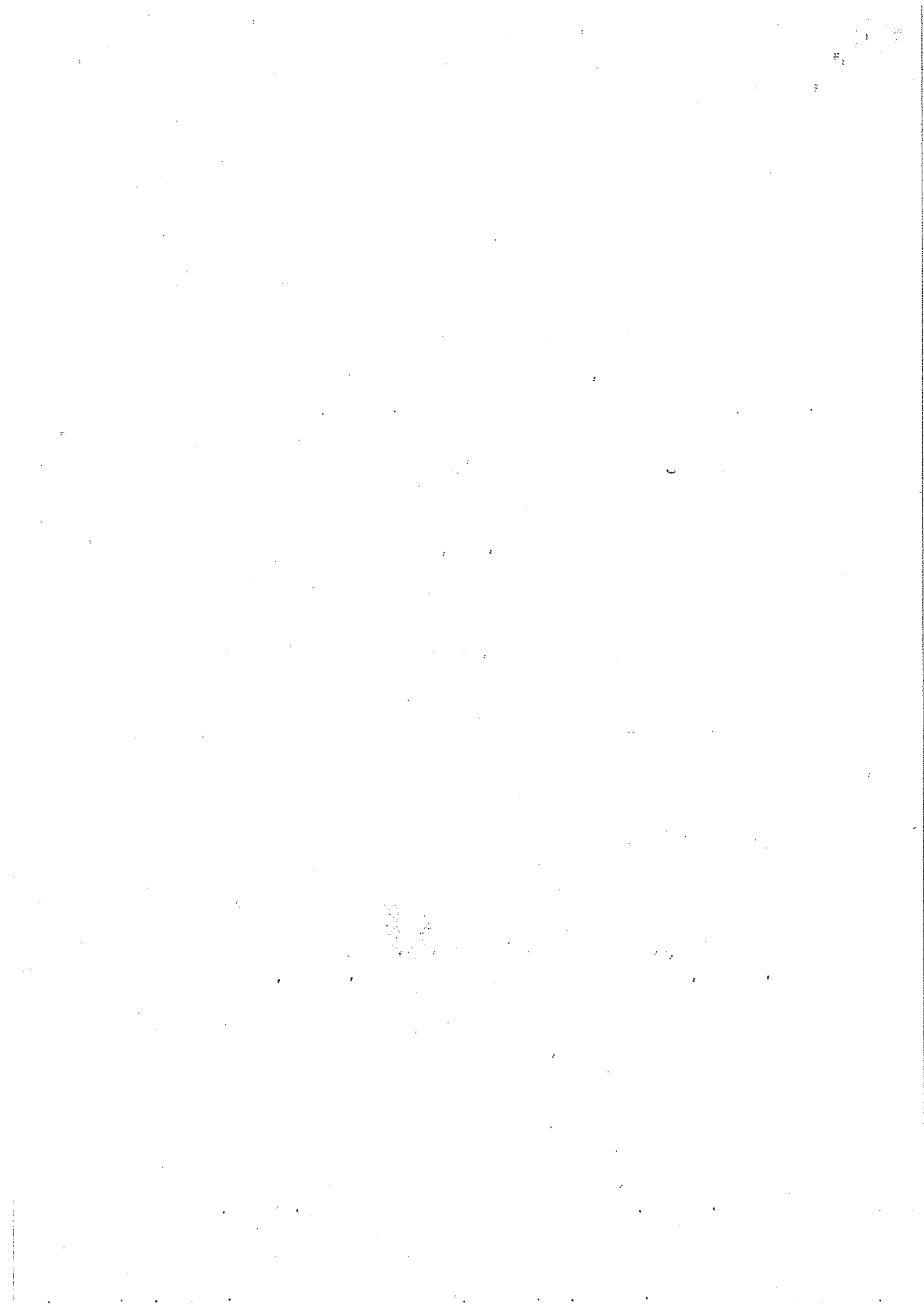
Place: New Delhi

Date: 06 JUN 2011




LICENSING AUTHORITY

Seal/Stamp
डा. सुरिन्द्र सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत) / Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Kotta Road,
New Delhi-110002



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

FDA Bhawan, New Delhi
Dated 06 JUN 2017

To,

M/S. WYETH LIMITED
LEVEL 6, PLATINA, PLOT NO. C-59,
'G'BLOCK, BANDRA-KURAL COMPLEX,
BANDRA(EAST)
MUMBAI-400051

Sub: -Registration of M/S. WYETH LEDERLE S.P.A VIA FRANCO GORGONE ZONA INDUSTRIALE 95100 CATANIA ITALY under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

Please refer to your application No. REG/WL/RC/11MP/108 dated 12/05/2011: received by this Office vide diary No : 23141 dated : 16/05/2011 on the above subject. Registration Certificate in Form 41 under the Rules is issued for 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.

- 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 ORIGINAL LABEL OF DRUG ALONG WITH PACKAGE INSERT SHALL BE SUBMITTED TO THIS OFFICE BEFORE IMPORT OF DRUG.
- 13 THE DILUENT MANUFACTURING SITE OF THIS DRUG IS AT M/S BEN VENUE LABOPRATORIES ,300 NORTHFIELD ROAD ,P.O BOX 46568 ,BEDFORD,OH 44146,USA.

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,

Drugs Controller General (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), Jawaharlal Nehru Port, Trust Nhava Seva Port, Raigard, Maharashtra.
5. The Assistant Drug Controller (I), International Air Cargo Complex, Indira Gandhi International Air Port, New Delhi-110037.



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. FF-519
DATED 05/08/2009 VALID UPTO 31/07/2012

ENDORSEMENT No. 1

*TEMSIROLIMUS 25MG/ML CONCENTRATE AND DILUENT
FOR SOLUTION FOR INFUSION

ITEMS (ONE) ONLY

*COPY OF PERMISSION OF RULE 122A SHALL BE SUBMITTED AT TIME OF
APPLICATION OF FORM TEN.

सत्यमेव जयते

Place: New Delhi

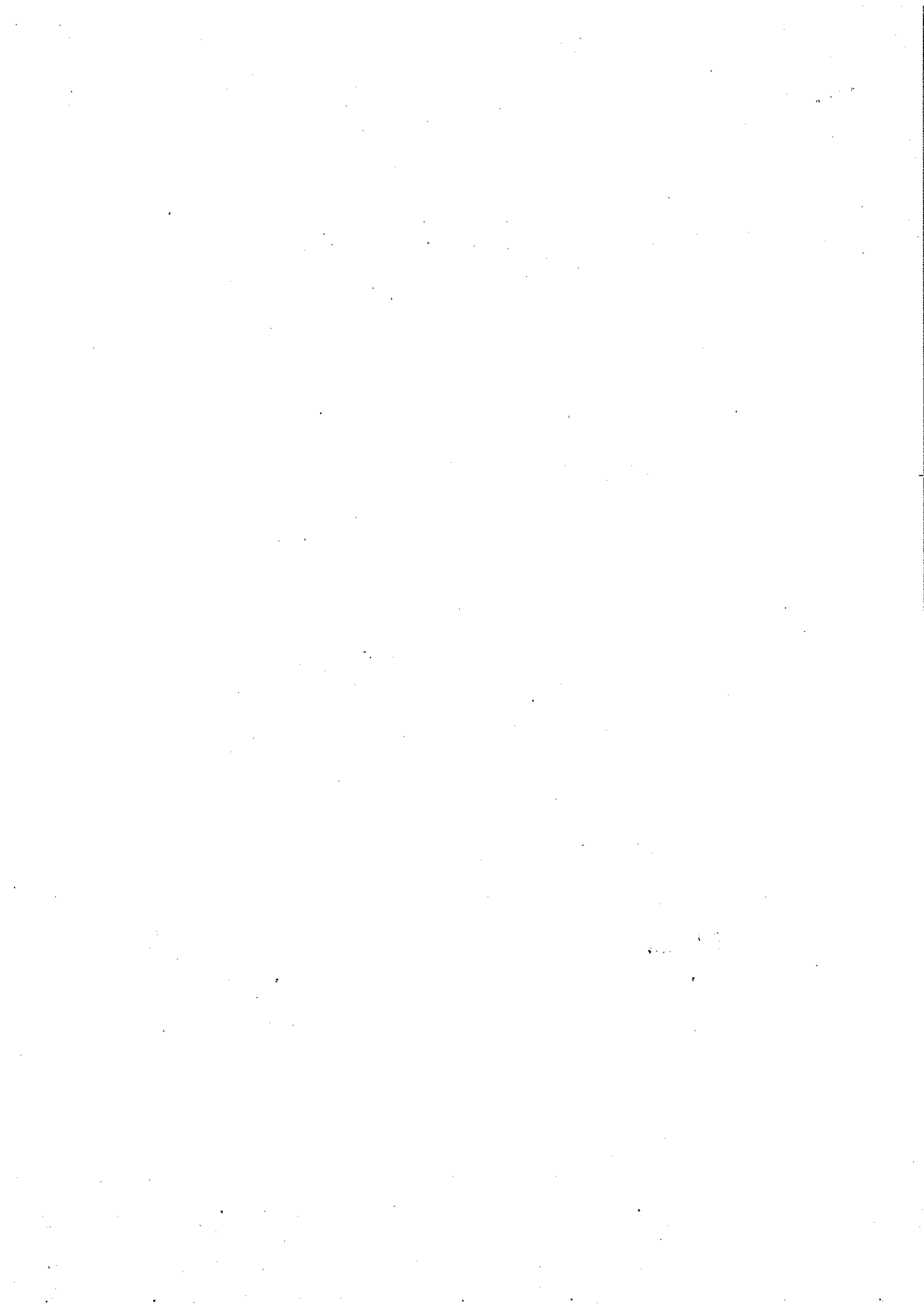
Date: 06 JUN 2011



LICENSING AUTHORITY

Seal/Stamp

डा. सुरिन्द्र सिंह
Dr. SURINDER SINGH
डीएच नियंत्रक (एनए) / Drugs Controller (India)
स्वास्थ्य सेवा पदाभिदेशासय
Dte. General of Health Services
FDA Bhawan, Kotta Road,
New Delhi-110002



No. 6-3/BD/16/2011-DC

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

FDA Bhawan, New Delhi
Dated 06 JUN 2011

To,

M/S. DIVINNE SBR INTERNATIONAL PRIVATE LTD.
FIRST FLOOR 7&8, MANGALDEEP
COMPLEX, NEAR LIZA CHAR RASTA
HIGH TENSION ROAD, SUBHANPURA,
VADODARA
TAL: VADODRA (VADODARA)

Sub: -Registration of M/S. CSPC ZHONGNUO PHARMACEUTICAL(SHI
IIAZHUANG) CO. LTD. NO. 6, HUAXING ROAD, ZHONGHUA SOUTH STREET,
SHIJIAZHUANG CITY 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. DI/FDA/DCGI/04042011/022-4 dated 17/05/2011, received by this Office vide diary no. 23635 dated 19/05/2011 on the above subject. Registration Certificate in Form 41 under the Rules is issued for the manufacturing site along with the name (s) of drug (s) imported under the said Certificate subject to the condition:

1. The drugs shall confirm 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.
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. **PRODUCT REGISTRATION CERTIFICATE ATTESTED BY CCPIT SHALL BE SUBMITTED TO THIS OFFICE BEFORE IMPORT OF DRUG.**
13. **THE SHELF LIFE OF DRUG IS 24 MONTHS AND BATCH SIZE IS 1000KG.**

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,

Drugs Controller General (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), Jawaharlal Nehru Port, Trust Nhava Seva Port, Raigard, Maharashtra.
5. The Assistant Drug Controller (I), International Air Cargo Complex, Indira Gandhi International Air Port, New Delhi-110037.



सत्यमेव जयते

GOVERNMENT OF INDIA

Central Drugs Standard Control Organisation Ministry of Health & Family Welfare FDA BHAWAN, NEW DELHI (INDIA)

Form 41

(See Rule 27-A)

REGISTRATION CERTIFICATE

Registration Certificate issued for import of drugs into India

Under Drugs and Cosmetics Rules, 1945

Registration Certificate No. BD-938

Dated

06 JUN 2011

1. M/S. CSPC ZHONGNUO PHARMACEUTICAL(SHI JIAZHUANG) CO. LTD. NO. 6, HUAXING ROAD, ZHONGHUA SOUTH STREET, SHIJIAZHUANG CITY CHINA having factory premises at M/s. CSPC ZHONGNUO PHARMACEUTICAL(SHI JIAZHUANG) CO. LTD. NO. 6, HUAXING ROAD, ZHONGHUA SOUTH STREET, SHIJIAZHUANG CITY CHINA has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.
2. Name(s) of drug(s), which may be imported under this Registration Certificate (Please refer the enclosed list of drugs).
3. This Registration Certificate shall be in force from 01/06/2011 to 31/05/2014 unless it is sooner suspended or cancelled under the rules.
4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/S DIVINNE SBR INTERNATIONAL PRIVATE LTD. FIRST FLOOR 7&8, MANGALDEEP COMPLEX, NEAR LIZA CHAR RASTA HIGH TENSION ROAD, SUBHANPURA, VADODARA TAL: VADODRA (VADODARA) who will be responsible for the business activities of the manufacturer in India in all respects.
5. This Registration Certificate is subject to the conditions stated overleaf and to such other conditions as may be specified in the Act and the Rules, from time to time.



Place: New Delhi

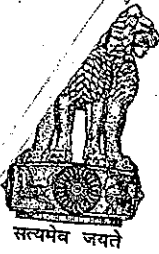
Date: 06 JUN 2011

LICENSING AUTHORITY

Seal/Stamp
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत) / Drugs Controller (India)
स्वास्थ्य सेवा महाविद्यालय
Dte. General of Health Services
FDA Bhawan, Kotla Road,
New Delhi-110002

Conditions of the Registration Certificate

1. The Registration Certificate shall be displayed at a prominent place by the authorised agent.
2. No drug shall be registered unless it has a free sale approval in the country of origin, and/or in other major countries.
3. The manufacturer or his authorised agent in India shall comply with the conditions of the import licence issued under the Drugs and Cosmetics Rules, 1945.
4. The manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed. The despatch and marketing of the drug in such cases shall be stopped immediately, and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of drug shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned drug in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours time period.
5. The manufacturer or his authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the drug pertaining to this Registration Certificate. In such cases, where there shall be any major change/modification in manufacturing, or in processing or in testing, or in documentation as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub rule (3) of rule 24-A.
6. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and /or address of the registered office/ factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises”.

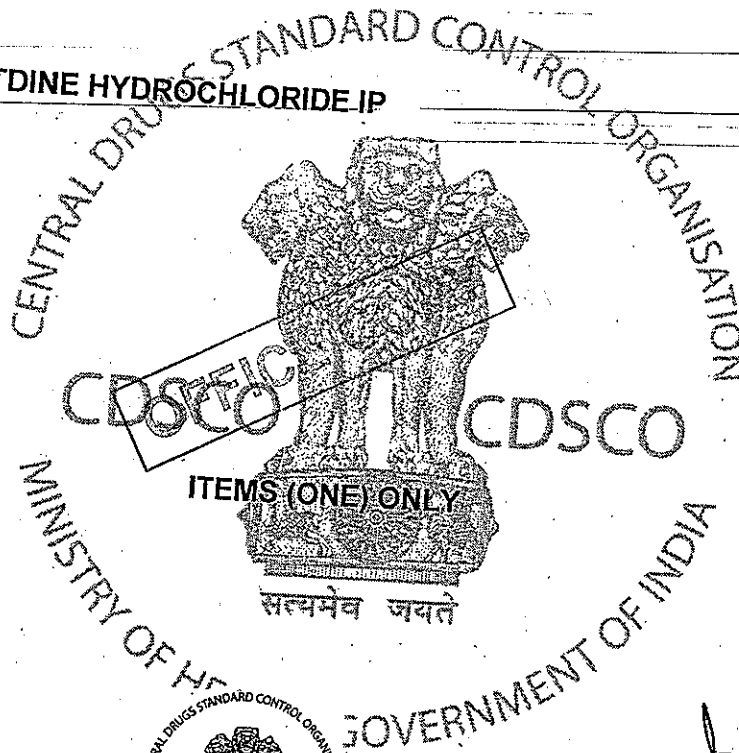


GOVERNMENT OF INDIA
 Central Drugs Standard Control Organisation
 Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED
 UNDER REGISTRATION CERTIFICATE NO. BD-938
 DATED 06 JUN 2011

RANITIDINE HYDROCHLORIDE IP



Place: New Delhi

Date: 06 JUN 2011



LICENSING AUTHORITY

डा. सुरिन्द्र सिंह Seal/Stamp
 Dr. SURINDER SINGH
 औषधि नियंत्रक (भारत)/Drugs Controller (India)
 स्वास्थ्य सेवा महानिदेशालय
 Dir. General of Health Services
 FDA Bhawan, Kofla Road,
 New Delhi-110002

No. 6-3/BD/05/08-DC(REREG2011)

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

FDA Bhawan, New Delhi
Dated 06 JUN 2011

To,

M/S. GREAT FORTUNE CHEMIE PHARMIE PVT. LTD.
612, KAMDHENU SHOPPING CENTRE
BLDG NO. 3, SWAMI SAMARTH NAGAR
ANDHERI(W)
MUMBAI-400053

Sub: -Registration of M/S. SHENZHEN HAIBIN PHARMACEUTICAL CO. LTD. NO. 2003, SHAYAN ROAD, YANTIAN DISTRICT, SHENZHEN P.R.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. NIL dated 16/05/2011, received by this Office vide diary no. 23687 dated 19/05/2011 on the above subject. Registration Certificate in Form 41 under the Rules is issued for 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.

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. **PRODUCT REGISTRATION CERTIFICATE ATTESTED BY CCPIT SHALL BE SUBMITTED TO THIS OFFICE BEFORE IMPORT OF DRUG.**

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.

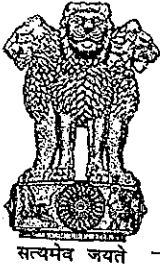
Please acknowledge the receipt.

Yours faithfully,

Drugs Controller General (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), Jawaharlal Nehru Port, Trust Nhava Seva Port, Raigard, Maharashtra.
5. The Assistant Drug Controller (I), International Air Cargo Complex, Indira Gandhi International Air Port, New Delhi-110037.



सत्यमेव जयते

GOVERNMENT OF INDIA

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

Form 41

(See Rule 27-A)

REGISTRATION CERTIFICATE

Registration Certificate issued for import of drugs into India

Under Drugs and Cosmetics Rules, 1945

Registration Certificate No. BD-737

Dated
06 JUN 2011

1.M/S. SHENZHEN HAIBIN PHARMACEUTICAL CO. LTD. NO. 2003, SHAYAN ROAD, YANTIAN DISTRICT, SHENZHEN P.R.CHINA having factory premises at M/s. SHENZHEN HAIBIN PHARMACEUTICAL CO. LTD. NO. 2003, SHAYAN ROAD, YANTIAN DISTRICT, SHENZHEN P.R.CHINA has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.

- Name(s) of drug(s), which may be imported under this Registration Certificate (Please refer the enclosed list of drugs).
- This Registration Certificate shall be in force from 01/08/2011 to 31/07/2014 unless it is sooner suspended or cancelled under the rules.
- This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/S GREAT FORTUNE CHEMIE PHARMIE PVT. LTD. 612, KAMDHENU SHOPPING CENTRE BLDG NO. 3, SWAMI SAMARTH NAGAR ANDHERI(W) MUMBAI-400053 who will be responsible for the business activities of the manufacturer in India in all respects.
- This Registration Certificate is subject to the conditions stated overleaf and to such other conditions as may be specified in the Act and the Rules, from time to time.



Place: New Delhi

Date: 06 JUN 2011

LICENSING AUTHORITY

Seal/Stamp
डा. सुरिन्द्र सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत) / Drugs Controller (India)
स्वास्थ्य सेवा महाविदेशालय
Dte. General of Health Services
FDA Bhawan, Kotia Road,
New Delhi-110002

Conditions of the Registration Certificate

1. The Registration Certificate shall be displayed at a prominent place by the authorised agent.
2. No drug shall be registered unless it has a free sale approval in the country of origin, and/or in other major countries.
3. The manufacturer or his authorised agent in India shall comply with the conditions of the import licence issued under the Drugs and Cosmetics Rules, 1945.
4. The manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed. The despatch and marketing of the drug in such cases shall be stopped immediately, and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of drug shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned drug in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours time period.
5. The manufacturer or his authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the drug pertaining to this Registration Certificate. In such cases, where there shall be any major change/modification in manufacturing, or in processing or in testing, or in documentation as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub rule (3) of rule 24-A.
6. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and /or address of the registered office/ factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises".



सत्यमेव जयते

GOVERNMENT OF INDIA

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED
UNDER REGISTRATION CERTIFICATE NO. BD-737
DATED 06 JUN 2011

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CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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ITEMS (ONE) ONLY

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MINISTRY OF HEALTH GOVERNMENT OF INDIA

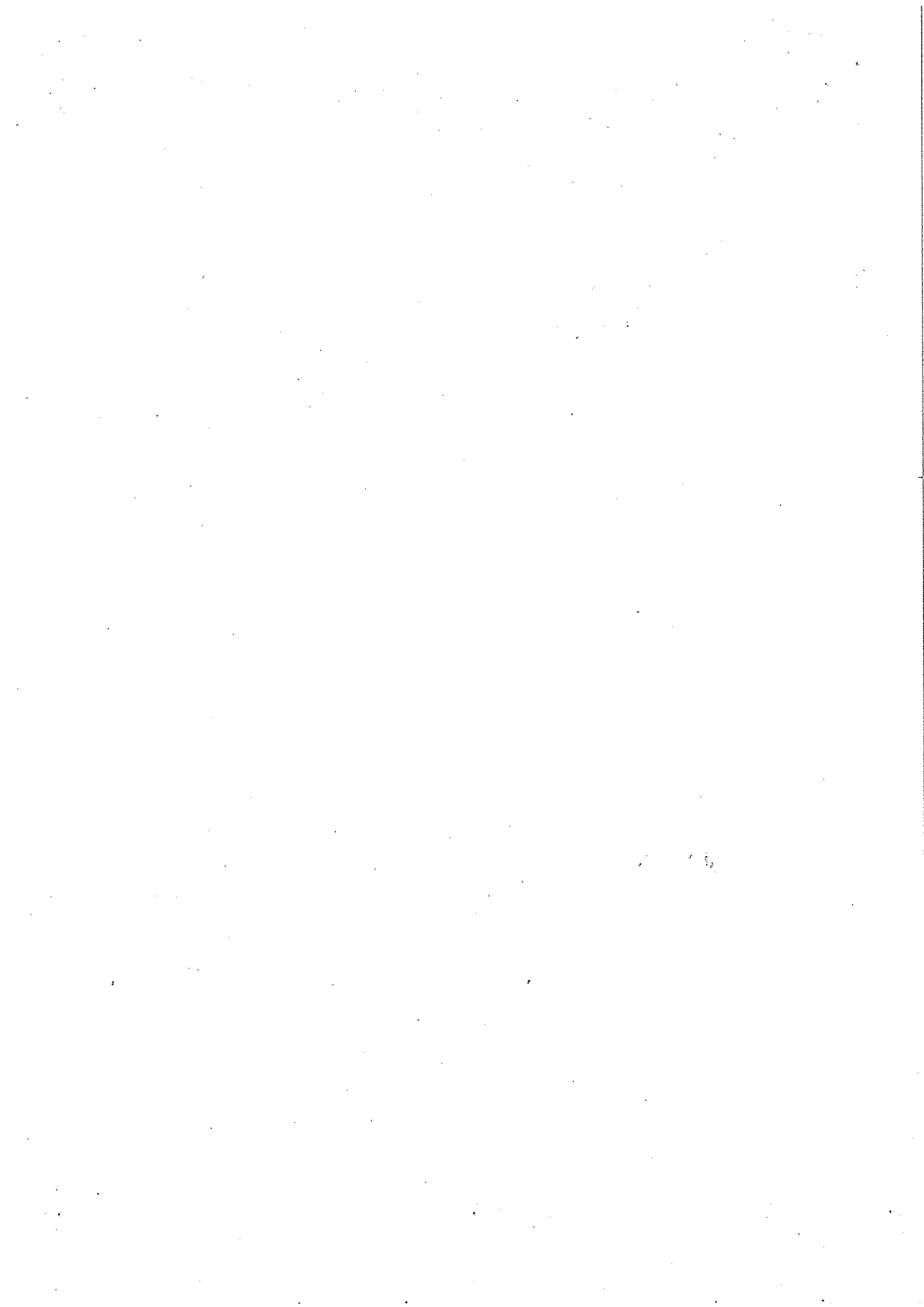


Place: New Delhi

Date: 06 JUN 2011

LICENSING AUTHORITY

डा. सुरिन्द्र सिंह/Stamp
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Kolla Road,
New Delhi-110002



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

FDA Bhawan, New Delhi
Dated

06 JUN 2011

To,

M/S. STALLEN SOUTH ASIA PRIVATE LIMITED
A/228, VIRAWANI INDUSTRIAL ESTATE,
OFF WESTERN EXPRESS HIGHWAY,
GOREGAONE(E)
MUMBAI-400063

Sub: -Registration of M/S. JIANGSU SEL BIOCHEM CORPORATION, LTD. NO. 98 YUEJIANG ROAD, NANTONG CITY, JIANGSU PROVINCE P.R. 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. NIL dated 18/08/2010, received by this Office vide diary no. 19091 dated 25/04/2011 on the above subject. Registration Certificate in Form 41 under the Rules is issued for the manufacturing site along with the name (s) of drug (s) imported under the said Certificate subject to the condition:

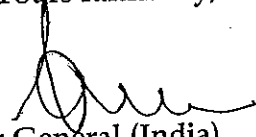
1. The drugs shall conform to the standards / specifications mentioned in the Second Schedule of the Act, or such other standards / specifications forwarded by you and approved by this Directorate.
2. The drugs shall have the composition, strengths, standards and packing as approved by this Directorate.
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.

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 BATCH SIZE OF DRUG IS 200KG AND SHELF LIFE OF DRUG IS 24 MONTHS.

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,


Drugs Controller General (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), Jawaharlal Nehru Port, Trust Nhava Seva Port, Raigard, Maharashtra.
5. The Assistant Drug Controller (I), International Air Cargo Complex, Indira Gandhi International Air Port, New Delhi-110037.



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GOVERNMENT OF INDIA
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare
FDA BHAWAN, NEW DELHI (INDIA)

Form 41

(See Rule 27-A)

REGISTRATION CERTIFICATE

Registration Certificate issued for import of drugs into India

Under Drugs and Cosmetics Rules, 1945

Registration Certificate No. BD-930

Dated

06 JUN 2011

1. M/S. JIANGSU SEL BIOCHEM CORPORATION, LTD. NO. 98 YUEJIANG ROAD, NANTONG CITY, JIANGSU PROVINCE P.R. CHINA having factory premises at M/s. JIANGSU SEL BIOCHEM CORPORATION, LTD. NO. 98 YUEJIANG ROAD, NANTONG CITY, JIANGSU PROVINCE P.R. CHINA has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.
2. Name(s) of drug(s), which may be imported under this Registration Certificate (Please refer the enclosed list of drugs).
3. This Registration Certificate shall be in force from 01/05/2011 to 30/04/2014 unless it is sooner suspended or cancelled under the rules.
4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/S STALLEN SOUTH ASIA PRIVATE LIMITED A/228, VIRAWANI INDUSTRIAL ESTATE, OFF WESTERN EXPRESS HIGHWAY, GOREGAONE(E) MUMBAI-400063 who will be responsible for the business activities of the manufacturer in India in all respects.
5. This Registration Certificate is subject to the conditions stated overleaf and to such other conditions as may be specified in the Act and the Rules, from time to time.



Place: New Delhi

Date: 06 JUN 2011

LICENSING AUTHORITY

डा. सुरेश सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत) / Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
PDA Bhawan, Kolla Road,
New Delhi-110002

Conditions of the Registration Certificate

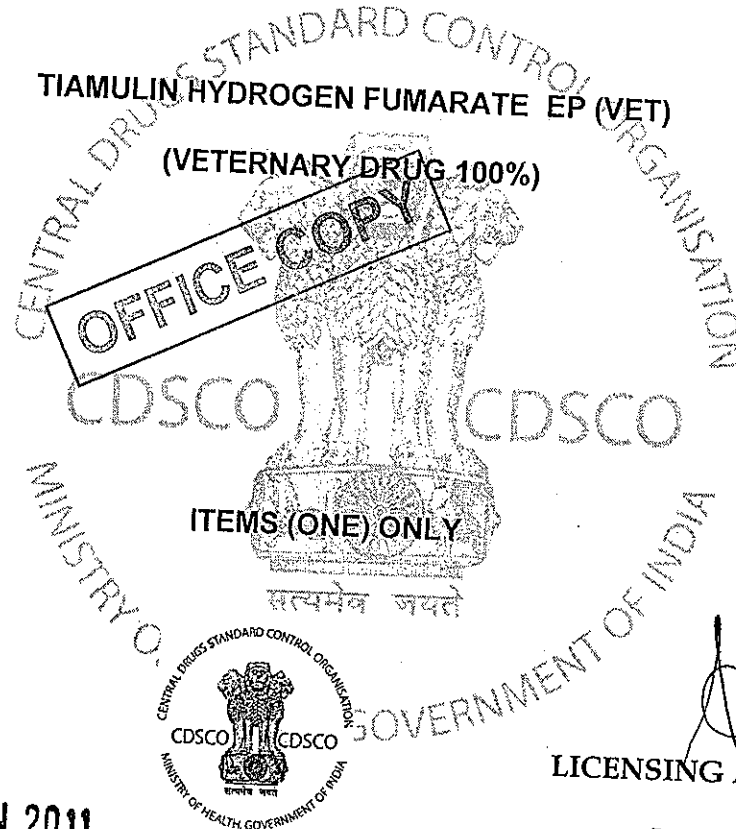
1. The Registration Certificate shall be displayed at a prominent place by the authorised agent.
2. No drug shall be registered unless it has a free sale approval in the country of origin, and/or in other major countries.
3. The manufacturer or his authorised agent in India shall comply with the conditions of the import licence issued under the Drugs and Cosmetics Rules, 1945.
4. The manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed. The despatch and marketing of the drug in such cases shall be stopped immediately, and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of drug shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned drug in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours time period.
5. The manufacturer or his authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the drug pertaining to this Registration Certificate. In such cases, where there shall be any major change/modification in manufacturing, or in processing or in testing, or in documentation as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub rule (3) of rule 24-A.
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सत्यमेव जयते

GOVERNMENT OF INDIA
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare
FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED
UNDER REGISTRATION CERTIFICATE NO. BD-930
DATED 06 JUN 2011



Place: New Delhi

Date: 06 JUN 2011

LICENSING AUTHORITY

Seal/Stamp
डा. सुरिन्द्र सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत) / Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
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