

No. 6-3/BD/89/2010-DC(Endorsement)-1

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

FDA Bhawan, New Delhi

Dated **11 NOV 2011**

To,

M/S. BHARAT SERUMS AND VACCINES LIMITED  
17TH FLOOR, HOESCHST HOUSE, NARIMAN  
POINT,  
MUMBAI-400021

Sub: -Registration of M/S. BSV BIOSCIENCE GmbH, MAX PLANCK STREET, 12, D-52499, BAESWEILER, GERMANY 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 18/03/2011: received by this Office vide diary No : 12872 dated : 18/03/2011 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 The drugs will be required to be withdrawn from sale from the market in case any undesirable reactions due to its medication are brought to light at any stage.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.

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.

OFFICE COPY

Yours faithfully,

V.G.S.

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, 2<sup>nd</sup> 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

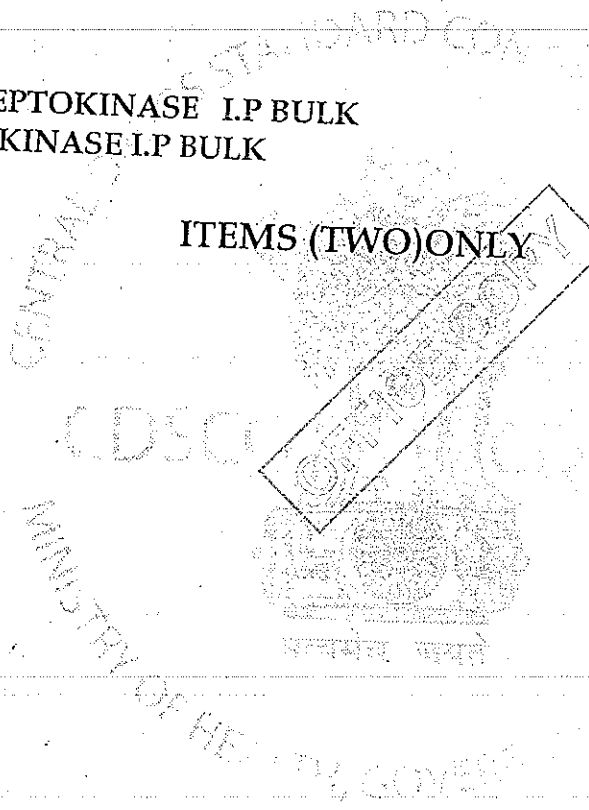
FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED  
UNDER REGISTRATION CERTIFICATE NO. BD-923  
DATED 06/05/2011 VALID UPTO 31/03/2014

ENDORSEMENT No. 1

1. STREPTOKINASE I.P BULK
2. UROKINASE I.P BULK

ITEMS (TWO) ONLY



Place: New Delhi

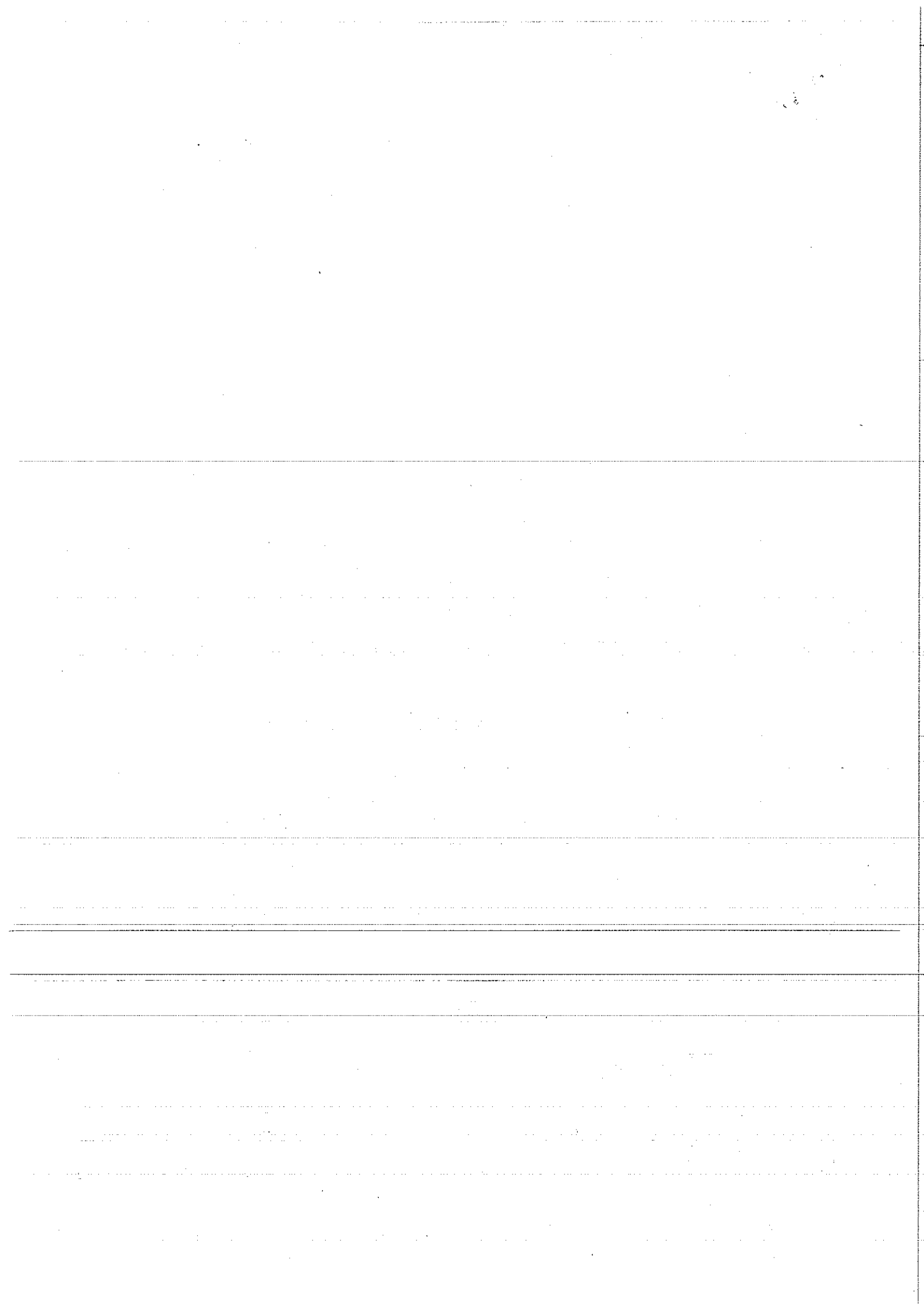
Date: 11 NOV 2011



V.G.S.

LICENSING AUTHORITY

डॉ. वेणुगोपाल खोसानी  
 Dr. V. G. Khosani, Seal/Stamp  
 महा आरोग्य विभाग (भारत)  
 Drugs Control Organisation (India)  
 स्वास्थ्य सेवा प्रशासन विभाग  
 Die. General Health Services  
 स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
 Ministry of Health & Family Welfare  
 एफ डी बी भवन, नई दिल्ली, आई.टी.ओ.  
 FDA Bhawan, Conna Road, I.T.O.  
 नई दिल्ली - 110 002 / New Delhi - 110 002



No. 6-3/BD/47/07-DC (RE-REGISTRATION - 2011)

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

FDA Bhawan, New Delhi

Dated

11 NOV 2011

To,

✓ M/S. ORGANON (INDIA) PRIVATE LIMITED  
7th FLOOR, PLATINA, PLOT NO. C-59,  
G-BLOCK, BANDRA KURLA COMPLEX,  
BANDRA (E), MUMBAI - 400 098

Sub: -Registration of M/S. N.V. ORGANON, VEERSEMEER 4, 5347 JN OSS, THE NETHERLANDS under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

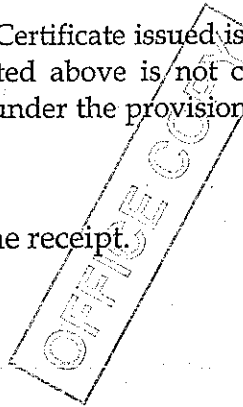
Please refer to your application no. NIL dated 25/10/2011, received by this Office vide diary no. 50018 dated 27/10/2011 on the above subject. Registration Certificate in Form 41 under the Rules is issued for the manufacturing site along with the name (s) of drug (s) imported under the said Certificate 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. Original labels of the products shall be submitted to this office before import.
13. Annual product review data of the product by the manufacturer shall be submitted to this office.

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.



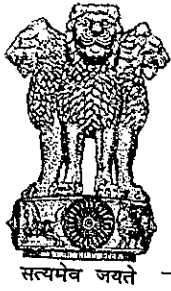
Yours faithfully,

V.G. Samant

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, 2<sup>nd</sup> 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-986

11 NOV 2011  
Dated

1. M/S. N.V. ORGANON, THE NETHERLANDS having factory premises at M/s. N.V. ORGANON, VEERSEMEER 4, 5347 JN OSS, THE NETHERLANDS 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 01/11/2011 to 31/10/2014 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. ORGANON (INDIA) PRIVATE LIMITED, 7th FLOOR, PLATINA, PLOT NO. C-59, G-BLOCK, BANDRA KURLA COMPLEX, BANDRA (E), MUMBAI - 400 098 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: 11 NOV 2011



V. G. Sen  
LICENSING AUTHORITY  
महा औषधि नियंत्रक (India)  
Drugs Controller General (India)  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Ministry of Health & Family Welfare  
एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ.  
FDA Bhawan, Kolla Road, I.T.O.  
110 002/New Delhi - 110

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".

DRUGS CONTROL  
INDIA  
NEW DELHI



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-986  
DATED 11 Nov. 2011



1. DESMOPRESSIN PH.EUR
2. DESOGESTREL PH.EUR
3. ESTRADIOL PH.EUR/USP
4. ETHINYLESTRADIOL IP
5. LEUPRORELIN PH.EUR
6. NALOXONE HYDROCHLORIDE IP
7. NORETHINDRONE IP
8. NORETHINDRONE ACETATE PH.EUR/USP
9. OXYTOCIN IP
10. PROGESTERONE PH. EUR

ITEMS (TEN) ONLY

Place: New Delhi

Date:

11 NOV 2011



LICENSING AUTHORITY

Dr. V. G. SOMANI  
 महा औषधि नियंत्रक (Seal/Stamp)  
 Drug Controller General  
 स्वास्थ्य सेवा महानिदेशालय  
 General of Health Services  
 सत्यमेव जयते  
 Ministry of Health & Family Welfare  
 नई दिल्ली



No. 6-3/BD/47(A)/07-DC (RE-REGISTRATION - 2011)

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

FDA Bhawan, New Delhi  
Dated **11 NOV 2011**

To,

M/S. ORGANON (INDIA) PRIVATE LIMITED  
7th FLOOR, PLATINA, PLOT NO. C-59,  
G-BLOCK, BANDRA KURLA COMPLEX,  
BANDRA (E), MUMBAI - 400 098

Sub: -Registration of M/S. N.V. ORGANON, KLOOSTERSTRAAT 6 5349 AB OSS, THE NETHERLANDS 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 25/10/2011, received by this Office vide diary no. 50019 dated 27/10/2011 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:

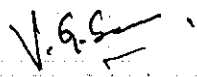
1. The drugs shall confirm to the standards / specifications mentioned in the Second Schedule of the Act, or such other standards / specifications forwarded by you and approved by this Directorate.
2. The drugs shall have the composition, strengths, standards and packing as approved by this Directorate.
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. Original labels of the products shall be submitted to this office before import.
13. Annual product review data of the product by the manufacturer shall be submitted to this office.

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.

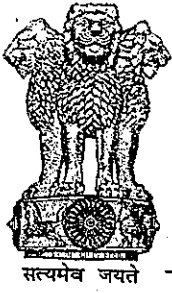
Please acknowledge the receipt.

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, 2<sup>nd</sup> 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

11 NOV 2011  
Dated

Registration Certificate No. BD-987

1. M/S. N.V. ORGANON, THE NETHERLANDS having factory premises at M/s. N.V. ORGANON, KLOOSTERSTRAAT 6 5349 AB OSS, THE NETHERLANDS 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 01/11/2011 to 31/10/2014 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. ORGANON (INDIA) PRIVATE LIMITED, 7th FLOOR, PLATINA, PLOT NO. C-59, G-BLOCK, BANDRA KURLA COMPLEX, BANDRA (E), MUMBAI - 400 098 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: 11 NOV 2011



V.G.S.

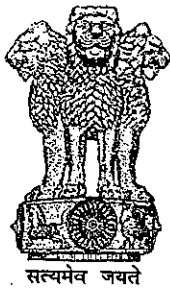
LICENSING AUTHORITY

डॉ. वेणुगोपाल खोसला  
Seal/Stamp

Dr. Venugopal Khosla  
Ministry of Health & Family Welfare  
एन.डी.ए. भवन, कोटला रोड, आई.टी.ओ.  
FDA Bhawan, Kotla Road, I.T.O.  
नई दिल्ली - 110 002/New Delhi - 110 002

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-987  
DATED **11 NOV 2011**

1. DESMOPRESSIN P.H.EUR
2. DESOGESTREL P.H.EUR
3. ESTRADIOL P.H.EUR/USP
4. ESTRIOL P.H.EUR/USP
5. ETHINYL ESTRADIOL IP
6. LEUPRORELIN PH.EUR
7. METHYLTESTOSTERONE P.H.EUR/USP
8. NORETHINDRONE IP
9. NORETHINDRONE ACETATE (P.H.EUR./USP)
10. OXYTOCIN IP
11. PROGESTERONE PH.EUR
12. NANDROLONE DECANOATE IP
13. NANDROLONE PHENYL PROPIONATE IP
14. TESTOSTERONE DECANOATE P.H.EUR
15. TESTOSTERONE ISOCAPROATE P.H.EUR
16. TESTOSTERONE PHENYL PROPIONATE
17. TESTOSTERONE PROPIONATE IP

ITEMS (SEVENTEEN) ONLY

Place: New Delhi

Date: **11 NOV 2011**



V.G.S.  
**LICENSING AUTHORITY**  
 Dr. V. G. ...  
 नरम औषधि नियंत्रक (भारत)  
 Drugs Controller General (India)  
 स्वास्थ्य सेवा, नई दिल्ली  
 स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
 Ministry of Health & Family Welfare  
 एफ.डी.ए. भवन, नई दिल्ली, ई.टी.ओ.  
 FDA Bhawan, New Delhi, I.T.O.  
 नई दिल्ली



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No. 6-4/FF/42/04-DC(REREG2010)

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

FDA Bhawan, New Delhi

Dated **11 NOV 2011**

To,

M/S. CHANDRA BHAGAT PHARMA PVT LIMITED  
323/F, BHAGAT BHUVAN DR. AMBEDKAR  
ROAD MATUNGA (EAST)  
MUMABI 400019

Sub: -Registration of M/S. SHANGHAI ZHONGXI SUNVE PHARMACEUTICAL CO LIMITED 50, YONG DENG ROAD SHANGHAI 200331 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. dated 14/09/2011, received by this Office vide diary no. 43298 dated 16/09/2011 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. ANNUAL PRODUCT REVIEW DATA OF LAST TWO YEARS BY MANUFACTURER.
13. 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,

V.G.S.

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, 2<sup>nd</sup> 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. FF-284

11 NOV 2011  
Date

1. M/S. SHANGHAI ZHONGXI SUNVE PHARMACEUTICAL CO LIMITED 50, YONG DENG ROAD SHANGHAI 200331 CHINA having factory premises at M/s. SHANGHAI ZHONGXI SUNVE PHARMACEUTICAL CO LIMITED 50, YONG DENG ROAD SHANGHAI 200331 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 01/09/2010 to 31/08/2013 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 CHANDRA BHAGAT PHARMA PVT LIMITED 323/F BHAGAT BHUVAN DR. AMBEDKAR ROAD MATUNGA (EAST) MUMABI 400019 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: 11 NOV 2011

V.G.S.

**REGISTRAR AUTHORITY**  
**Dr. V. G. SOMANI**  
 महा औषधि नियंत्रक (भारत)  
 Drugs Controller (India)  
 स्वास्थ्य सेवा महा निदेशालय  
 Director General of Health Services  
 सत्यमेव जयते

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".



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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-284  
DATED 11 NOV 2011

PYRIDOSTIGMINE BROMIDE 60 mg TABLET

OFFICE COPY  
ITEMS (ONE) ONLY

Place: New Delhi

Date: 11 NOV 2011



V.G.S.

LICENSING AUTHORITY

Dr. V. G. SOMANI  
महा औषधि नियंत्रक (एनडी)  
Drugs Controller General (India)

स्वास्थ्य सेवा महानिदेशालय  
Dte. General of Health Services

स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Ministry of Health & Family Welfare  
एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ.  
FDA Bhawan, Kotla Road, I.T.O.

नई दिल्ली - 110 002/New Delhi - 110 002

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No. 6-3/BD/35/06-DC (RE-REGISTRATION 2009) ENDORSMENT

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

FDA Bhawan, New Delhi

Dated **11 NOV 2011**

To,

M/S. Igenerix Pharma Pvt Limited  
1202, ATSGreensVillageExpressway Sector 93-A  
Noida-201-301, UP

Sub: -Registration of M/S. Uquifa Mexico S.A. de, C.V., Calle 37 Este NO. 126, C.P. 62500 Civac Jiutepec, Morelos Mexico 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 10/05/2010: received by this Office vide diary No : 22047 dated : 10/05/2010 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 ANNUAL PRODUCT REVIEW DATA OF LAST TWO YEARS BY MANUFACTURER SHALL BE SUBMITTED TO THIS OFFICE.**

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.G.S.

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, 2<sup>nd</sup> 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)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED  
UNDER REGISTRATION CERTIFICATE NO. BD-603  
DATED 16/02/2010 VALID UPTO 31/05/2012

ENDORSEMENT No. 1

ALBENDAZOLE IP(BULK)

ITEM (ONE) ONLY

OFFICE COPY

Place: New Delhi

Date: 11 NOV 2011



V.G.S.  
LICENSING AUTHORITY  
महा औषधि नियंत्रक (भारत)  
Drugs Controller General (India)  
स्वास्थ्य सेवा महाविभाग  
Dte. General of Health Services  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Ministry of Health & Family Welfare  
एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ.  
FDA Bhawan, Kotta Road, I.T.O.  
नई दिल्ली - 110 002/New Delhi - 110 002

TO: DIRECTOR, FBI  
FROM: SAC, NEW YORK  
SUBJECT: [Illegible]

RE: [Illegible]

DATE: [Illegible]