

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

New Delhi, dated

To:

**03 FEB 2011**

M/s. Trade Impex International  
40-B, Mangaldas Bldg. No. 1  
2nd Floor, Princess Street  
Mumbai-400002

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. Nil Dated 05/01/2011 received by this office vide diary no. 1252 dt. 10/01/2011, I enclose licence(s) Nos. BD-404-18461 dated 03 FEB 2011. These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

**03 FEB 2011**

  
Assistant Drug Controller (India)

No. 6-3/BD/07/04-DC(Re-Reg-2010)

Copy together with copy of Licence No. BD-404-18461 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-404-18461

Date 03 FEB 2011

1. M/S. Trade Impex International 40-B, Mangaldas Bldg. No. 1 2nd Floor, Princess Street Mumbai-400002 is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. Hubei Huazhong Pharmaceutical Co. Ltd., No. 71, West Chunyuan Road, Xiangfan City, Hubei Province China any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from 28/01/2011 to 31/08/2011 unless it is sooner suspended or cancelled under the said rules.

Names of drugs to be imported

1. Thiamine Hydrochloride IP (Vitamin B1 Hydro Chloride)

2. Thiamine Mononitrate IP (Vitamin B1 Mononitrate)

Item (Two) Only

Place: New Delhi

Date: 03 FEB 2011

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

LICENSING AUTHORITY

ARVIND KUKRETY

सहायक अंशुषि (विशेषक) (भारत)

Assistant Drugs Controller (India)

स्वास्थ्य सेवा विभाग

Seal/Stamp  
Directorate General of Health Services  
F.D.A. Bhawan, Kolla Road  
New Delhi-110 002

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

New Delhi, dated

To:

03 FEB 2011

M/s. Rupal Chemicals  
Aldun Bldg, "B" Shop No. 1,  
Ground Floor, Dhobi Talao  
Mumbai-400002

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. Nil Dated 05/01/2011 received by this office vide diary no. 1480 dt. 11/01/2011, I enclose licence(s) Nos. BD-16-18462 dated 11/01/2011. This licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

  
Assistant Drug Controller (India)

03 FEB 2011

No. 6-3/BD/23/02-DC(Pt-1) (Re-Reg-2008)

Copy together with copy of Licence No. BD-16-18462 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-16-18462

Date 03 FEB 2011

1. M/S. Rupal Chemicals Aldun Bldg, "B" Shop No. 1, Ground Floor, Dhobi Talao Mumbai-400002 is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. BASF SE, Carl- Bosch-Strasse 38, 67056 Ludwigshafen, Germany any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

OFFICE COPY

2. This licence shall be in force from 28/01/2011 to 31/12/2011 unless it is sooner suspended or cancelled under the said rules.

Names of drugs to be imported


1. Vitamin A Palmitate 1.7 MIO BP

2. Vitamin A Palmitate 1.0 MIO BP

Item (Two) Only

Place: New Delhi

Date 03 FEB 2011

  
LICENSING AUTHORITY  
ARVIND KUMAR  
सहायक औषधि नियंत्रक (भारत)  
Assistant Drugs Controller (India)  
स्वास्थ्य सेवा महाविद्यालय  
Seal/Stamp  
Directorate General of Services  
F.D.A. Bhawan, Kolla Road  
New Delhi - 110 002

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

To:

New Delhi, dated

03 FEB 2011

M/s. Pharma Force Lab  
53/55, Industrial Area  
Paonta Sahib-173025

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

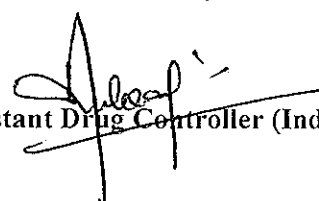
Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. Nil Dated 22/01/2011 received by this office vide date no. 3567 dt. 24/01/2011, I enclose licence(s) Nos. BD-745-18463 dated 03 FEB 2011. This/These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

OFFICE COPY

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

  
Assistant Drug Controller (India)

03 FEB 2011

No. 6-3/BD/03/08-DC

Copy together with copy of Licence No. BD-745-18463 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-745-18463

Date 03 FEB 2011

1. M/S. Pharma Force Lab 53/55, Industrial Area Paonta Sahib-173025 is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. Zhejiang Starry Pharmaceutical Co. Ltd. Sanqiao Chengguan Town, Xianju County, Taizhou, Zhejiang China any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

OFFICE COPY

2. This licence shall be in force from 28/01/2011 to 31/08/2011 unless it is sooner suspended or cancelled under the said rules.


Names of drugs to be imported

Levofloxacin IP

Item (One) Only

Place: New Delhi

Date: 03 FEB 2011

  
LICENSING AUTHORITY

अरविन्द कुकरेती  
ARVIND KUKRETY  
सहायक औषधि नियंत्रक (भारत)  
Assistant Drug Controller (India)  
रक्षास्थल सेवा महानिदेशालय  
Seal/Stamp

Conditions of Licence

Directorate General of Health Services  
F.D.A. Bhawan, Kotla Road  
New Delhi

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

New Delhi, dated

To:

03 FEB 2011

M/s. Alkem Laboratories Limited,  
Vill. Thana, Baddi,  
Distt. Solan

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. ALK-10/01/11 Dated 11/01/2011 received by this office vide 03 FEB 2011 no. 1493 dt. 11/01/2011, I enclose licence(s) Nos. BD-827-18464 dated 03 FEB 2011. This/These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce. **OFFICE COPY**
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

03 FEB 2011

  
Assistant Drug Controller (India)

No. 6-3/BD/97/09-DC

Copy together with copy of Licence No. BD-827-18464 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic

Rules, 1945

Licence Number BD-827-18464

Date 03 FEB 2011

1. M/S. Alkem Laboratories Limited, Vill. Thana, Baddi, Distt. Solan is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. Hec Biochem Co. Ltd., 62, Binjiang Road, Yidu City, Hebei Province P.R.China- 443300 any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.
2. This licence shall be in force from 28/01/2011 to 28/02/2013 unless it is sooner suspended or cancelled under the said rules.

Names of drugs to be imported


**Azithromycin Dihydrate IP**

Item (One) Only

Place: New Delhi

Date: 03 FEB 2011

OFFICE COPY

  
LICENSING AUTHORITY  
अरविंद कुरेती  
ARVIND KURETY  
सहायक औषधि नियंत्रक (भारत)  
Assistant Drugs Controller (India)  
स्वास्थ्य सेवा विभाग  
Directorate General of Health Services  
F.D.A. Bhawan, Kotla Road  
New Delhi-110 002

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

To:

New Delhi, dated

03 FEB 2011

M/s. Macleods Pharmaceuticals Limited(Phase-II)  
Plot No. 25-27, Survey No. 366, Premier Industrial Estate, kachigam  
Daman-396210

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

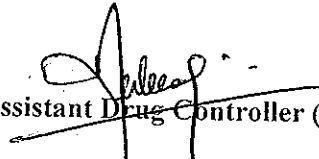
Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. Nil Dated 04/01/2011 received by this office vide diary no. 1478 dt. 11/01/2011, I enclose licence(s) Nos. BD-791-18465 dated 03 FEB 2011. This/These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and ~~distinct from~~ any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

03 FEB 2011

  
Assistant Drug Controller (India)

No. 6-3/BD/50/07-DC

Copy together with copy of Licence No. BD-791-18465 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-791-18465

Date 03 FEB 2011

1. M/S. Macleods Pharmaceuticals Limited(Phase-II) Plot No. 25-27, Survey No. 366, Premier Industrial Estate, kachigam Daman-396210 is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. Jiangsu Yongda Pharmaceutical Co. Ltd. No. 38 Zhenli Road Huangtu Town Jiangyin City, P.R.China any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.
2. This licence shall be in force from 28/01/2011 to 31/05/2012 unless it is sooner suspended or cancelled under the said rules.

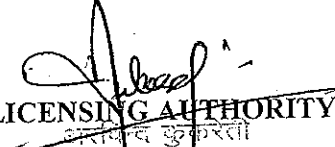
Names of drugs to be imported

**Gatifloxacin IP**

**Item (One) Only**

Place: New Delhi

Date: 03 FEB 2011

  
**LICENSING AUTHORITY**  
सहायक ड्रग्स कंट्रोलर  
ARVIND KURETY  
सहायक ड्रग्स नियंत्रक (भारत)  
Assistant Drugs Seal/Stamp  
स्वास्थ्य सेवा महानिदेशालय  
Director General of Health Services  
F.D.A. Bhawan, Kola Road  
New Delhi-110 002

**Conditions of Licence**

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

New Delhi, dated

To:

03 FEB 2011

M/s. Orbit Impex  
Gala No. 2, Bld, No. G Hissa No. 2 Survey No. 122  
Munisurat Complex Phase-II Rahnal, Bhiwandi-Thane  
Tal: Bhiwandi(Thane-Zone)

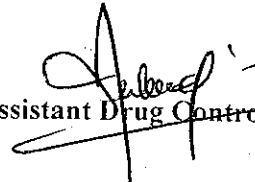
**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. Nil Dated 28/12/2010 received by this office vide diary no. 1500 dt. 11/01/2011, I enclose licence(s) Nos. BD-687-18466 dated 03 FEB 2011. These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

- OFFICE COPY**
1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
  2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
  3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
  4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
  5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
  6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

  
Assistant Drug Controller (India)

03 FEB 2011

No. 6-3/BD/46/07-DC(re-reg-2010)

Copy together with copy of Licence No. BD-687-18466 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic

Rules, 1945

03 FEB 2011

Licence Number BD-687-18466

Date \_\_\_\_\_

1. M/S. Orbit Impex Gala No. 2, Bld, No. G Hissa No. 2 Survey No. 122 Munisurat Complex Phase-II Rahnal, Bhiwandi-Thane Tal: Bhiwandi(Thane-Zone) is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. Shandong New Time Pharmaceutical Co. Ltd. No. 01-North, Outer Ring Road, Feixian County, Shandong China any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from 28/01/2011 to 31/08/2013 unless it is sooner suspended or cancelled under the said rules.

Names of drugs to be imported


1. **Clavulanate Potassium With Silicon Dioxide USP(1:1)**

2. **Clavulanate Potassium With Microcrystalline Cellulose USP(1:1)**

Item (Two) Only

Place: New Delhi

Date: 03 FEB 2011

  
**LICENSING AUTHORITY**  
ARVIND KUKRETY  
सहायक औषधि नियंत्रक (भारत)  
Assistant Drugs Controller (India)  
स्वास्थ्य सेवा विभाग  
Seal/Stamp  
Directorate General of Health Services  
F.D.A. Bhawan, Kotla Road  
New Delhi-110 002

**Conditions of Licence**

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

New Delhi, dated

To:

03 FEB 2011

M/s. Elder Pharmaceuticals Ltd.  
Elder House, C/9, Dalia Industrial Estate,  
Off veera Desai Road, Andheri(West)  
Mumbai-400058

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. SK/RP/207/2011 Dated 10/01/2011 received by this office vide diary no. 1463 dt. 11/01/2011, I enclose licence(s) Nos. BD-892-18467 dated 03 FEB 2011 these licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

03 FEB 2011

Assistant Drug Controller (India)

No. 6-3/BD/05/04-DC(Pt-1) (Re-reg-2010)

Copy together with copy of Licence No. BD-892-18467 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-892-18467

Date 03 FEB 2011

1. M/S. Elder Pharmaceuticals Ltd. Elder House, C/9, Dalia Industrial Estate, Off  
veera Desai Road, Andheri(West) Mumbai-400058 is hereby licensed into India  
during the period for which this licence is in force, the drugs specified below,  
manufactured By M/s. Nuvo Manufacturing GmbH, Vor Dem Schlosstor 9, 39164  
Wanzleben, Germany any other drugs manufactured by the said manufacturer as  
may from time to time be endorsed on this licence.

2. This licence shall be in force from 28/01/2011 to 30/11/2013 unless it is sooner  
suspended or cancelled under the said rules.

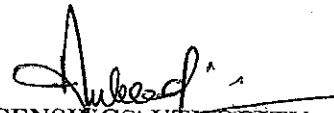
Names of drugs to be imported

Tetrachlorodecaoxygen(TCDO) Solution

Item (One) Only

Place: New Delhi

Date : 03 FEB 2011

  
**LICENSING AUTHORITY**  
ARVIND KUKRETY  
सहायक औषधि नियंत्रक (भारत)  
Assistant Drugs Controller (India)  
स्वास्थ्य विभाग  
Seal/Stamp  
Directorate General of Health Services  
F.D.A. Bhawan, Kotla Road  
New Delhi-110 002

**Conditions of Licence**

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

To:

M/s. Elder Pharmaceuticals Ltd.  
Elder House, C/9, Dalia Industrial Estate,  
Off veera Desai Road, Andheri(West)  
Mumbai-400058

New Delhi, dated  
03 FEB 2011

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

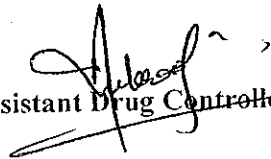
Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. SK/RP/208/2011 Dated 10/01/2011 received by this office vide no. 1464 dt. 11/01/2011, I enclose licence(s) Nos. BD-467-18468 dated 03 FEB 2011. This/These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

03 FEB 2011

  
Assistant Drug Controller (India)

No. 6-3/BD/104/04-DC (Re-reg-2010)

Copy together with copy of Licence No. BD-467-18468 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-467-18468

Date 03 FEB 2011

1. M/S. Elder Pharmaceuticals Ltd. Elder House, C/9, Dalia Industrial Estate, Off  
veera Desai Road, Andheri(West) Mumbai-400058 is hereby licensed into India  
during the period for which this licence is in force, the drugs specified below,  
manufactured By M/s. Interquim S.A. Joan Buscalla No. 10,08173 Sant Cugat  
Del Valles (Barcelona) Spain any other drugs manufactured by the said  
manufacturer as may from time to time be endorsed on this licence.
2. This licence shall be in force from 28/01/2011 to 31/12/2013 unless it is sooner  
suspended or cancelled under the said rules.

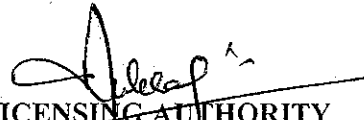
Names of drugs to be imported

1. Citicholine Monosodium Salt
2. Sertaconazole Nitrate

Item (Two) Only

Place: New Delhi

Date: 03 FEB 2011

  
LICENSING AUTHORITY  
अरविन्द कुकरेती  
ARVIND KUKRETY  
सहायक औषधि नियंत्रक (भारत)  
Assistant Drugs Controller (India)  
स्वास्थ्य सेवा महानिदेशालय  
Corporate General of Health Services  
F.D.A. Bhawan, Kolla Road

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

To:

New Delhi, dated

03 FEB 2011

M/s. Medi Pharma Drug House  
Bulakhidas Bldg, Gr. Floor, 13,  
Vithaladas Road, Princess Street,  
Mumbai-400002

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. FM/50/10 Dated 07/01/2011 received by this office vide diary no. 1418 dt. 11/01/2011, I enclose licence(s) Nos. BD-893-18469 dated 03 FEB 2011. These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

- OFFICE COPY
1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
  2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
  3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
  4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
  5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
  6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

03 FEB 2011

  
Assistant Drug Controller (India)

No. 6-3/BD/71/2010-DC

Copy together with copy of Licence No. BD-893-18469 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-893-18469

Date 03 FEB 2011

1. M/S. Medi Pharma Drug House Bulakhidas Bldg, Gr. Floor, 13, Vithaladas Road, Princess Street, Mumbai-400002 is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. Suzhou Wugan Pharmaceutical Co. Ltd. No. 1 Dongguan Road, Tuncun District. Tongli Town Wujin AG City, Jiangsu China any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

OFFICE COPY

2. This licence shall be in force from 28/01/2011 to 30/11/2013 unless it is sooner suspended or cancelled under the said rules.

Names of drugs to be imported

Sulfadiazine IP Vet

Item (One) Only

Place: New Delhi

Date : 03 FEB 2011

LICENSING AUTHORITY

ARVIND KUMRETY  
रक्षक औषधि नियंत्रक (देश)  
Assistant Drug Controller (India)  
स्वास्थ्य सेवा विभाग

Seal/Stamp

Directorate General of Health Services  
F.D.A. Bhawan, Kotla Road  
New Delhi-110 002

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

To:

03 FEB 2011 New Delhi

M/s. Orbit Lifescience Pvt. Ltd.  
Gala No. 1, Building No. G. Ground Floor, Phase-II Munisurat Complex,  
Survey No. 122. Village Rehnal, Bhiwandi Dist. Thane  
Tal: Bhiwandi(Thane-Zone)

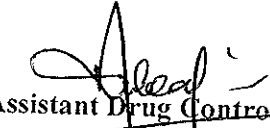
**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. Nil Dated 28/12/2010 received by this office vide diary no. 1501 dt. 11/01/2011, I enclose licence(s) Nos. BD-687-18470 dated 03 FEB 2011. These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

  
Assistant Drug Controller (India)

03 FEB 2011

No. 6-3/BD/46/07-DC(Re-Reg-2010

Copy together with copy of Licence No. BD-687-18470 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-687-18470

Date 03 FEB 2011

1. M/S. Orbit Lifescience Pvt. Ltd. Gala No. 1, Building No. G. Ground Floor,  
Phase-II Munisurat Complex, Survey No. 122. Village Rehnal, Bhiwandi Dist.  
Thane Tal: Bhiwandi(Thane-Zone) is hereby licensed into India during the period  
for which this licence is in force. The drugs specified below, manufactured By M/s.  
Shandong New Time Pharmaceutical Co. Ltd. No. 1, North Outer Ring Road,  
Feixian County, Shandong China any other drugs manufactured by the said  
manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from 28/01/2011 to 31/08/2013 unless it is sooner  
suspended or cancelled under the said rules.

Names of drugs to be imported

1. Clavulanate Potassium With Silicon Dioxide USP(1:1)
2. Clavulanate Potassium With Microcrystalline Cellulose USP (1:1)

Item (Two) Only

Place: New Delhi

Date : 03 FEB 2011

  
LICENSING AUTHORITY

Assistant Director (India)  
Seal/Stamp  
Directorate General Health Services  
F.D.A. Buzwan, Kaila Road  
New Delhi - 110 002

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

To:

New Delhi, dated  
03 FEB 2011

M/s. Parabolic Drugs Ltd.  
Village Sundhran, P.O. Mubarakpur,  
Tehsil Dera Bassi,  
District Mohali

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. Nil Dated 07/01/2011 received by this office vide No. 1503 dt. 11/01/2011, I enclose licence(s) Nos. BD-605-18471 dated 03 FEB 2011. This/These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

OFFICE COPY

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

03 FEB 2011

Assistant Drug Controller (India)

No. 6-3/BD/39/06-DC(Pt-1) (Re-Reg-2009)

Copy together with copy of Licence No. BD-605-18471 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-605-18471

Date 03 FEB 2011

1. M/S. Parabolic Drugs Ltd. Village Sundhran, P.O. Mubarakpur, Tehsil Dera Bassi, District Mohali is hereby licensed into India during the period for which this licence is in force, the drugs specified below manufactured By M/s. Zhejiang Xinhua Pharmaceutical Co. Ltd., The Base of Chemical Bulk Drug, Linhai District, Zhejiang Province China any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from 28/01/2011 to 31/05/2012 unless it is sooner suspended or cancelled under the said rules.


Names of drugs to be imported

Ampicillin Sodium With Sulbactam Sodium USP

Item (One) Only

Place: New Delhi

Date : 03 FEB 2011

  
**LICENSING AUTHORITY**  
अरविंद कुक्रेती  
ARVIND KUKRETI  
सहायक औषधि निदेशक (भारत)  
Assistant Drugs **Seal/Stamp**  
केंद्र, सेवा महाविद्यालय  
Directorate General of Health Services  
F.D.A. Bhawan, Kaila Road  
002

**Conditions of Licence**

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";

From:

The Drugs Controller (India)  
Directorate General of Health Services  
FDA Bhawan, Kotla Road  
Phone No.-011-23236965, Fax No.-23236973

To:

New Delhi, dated  
03 FEB 2011

M/s. J.B. Khokhani & Co.  
Survey No. 50, Hissa No. 4, Gala No. 6, 1st Fl. Thakkar Comp.  
Val Village, Anjur Road,  
Bhiwandi

**Sub: Import Licence under the Drugs Act, 1940 and Drugs Rules thereunder.**

Dear Sir/Sirs,

With reference to your application for import licence forwarded to this office with your letter No. Nil Dated 07/01/2011 received by this office vide diary no. 1366 dt. 11/01/2011, I enclose licence(s) Nos. BD-825-18472 dated 03 FEB 2011. These licence(s) has/have been under the Drugs Act, 1940 and Rules thereunder.

1. I am to point out the provisions of Drugs Act, 1940 are in addition to and not derogation of any other law for the time being in force and as such the licences issued under Drugs Act will be in addition to and distinct from any licences which may be necessary under the Import Trade Control Regulations made of the Government of India, Ministry of Commerce.
2. The import licence(s) mentioned in para (1) above will not accordingly to itself/themselves be sufficient authority for import of Drugs covered by that/those licence if under the Import Trade Control Regulations of the Commerce Ministry separate licences are required for import of such drug(s).
3. I am therefore, to advise you to obtain, where necessary licences for import of drugs in question under the Import Trade Control Regulations.
4. Any literature or packing accompanying the drug or any matter stated on the label should not contravene the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act.
5. The Assistant Drugs Controller (India) and Technical Officer of the Central Organization at the ports will be Officers authorized to inspect the premises of importers establishments for the purpose of Rule 26 of the Drugs Rules.
6. Please acknowledge receipt of this letter and its enclosures.

Yours faithfully,

  
Assistant Drug Controller (India)

No. 6-3/BD/86/09-DC

Copy together with copy of Licence No. BD-825-18472 dated

1. Asstt. Drugs Controller (India), New Customs, Fort, Mumbai.
2. Asstt. Drugs Controller (India), Customs House, Kolkata.
3. Asstt. Drugs Controller (India), Customs House, Chennai.
4. Asstt. Drugs Controller (India), IGIA, New Delhi.

FORM 10  
(See rules 23 and 27)

Licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic  
Rules, 1945

Licence Number BD-825-18472

Date 03 FEB 2011

1. M/S. J.B. Khokhani & Co. Survey No. 50, Hissa No. 4, Gala No. 6, 1st Fl. Thakkar Comp. Val Village, Anjur Road, Bhiwandi is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. Henan Topfond Pharmaceutical Co. Ltd. No. 1219, Jiaotong Road, Zhumadian, Henan 463000 China and other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.
2. This licence shall be in force from 28/01/2011 to 31/01/2013 unless it is sooner suspended or cancelled under the said rules.

Names of drugs to be imported

**Ofloxacin IP**

**Item (One) Only**

Place: New Delhi

Date: 03 FEB 2011

**LICENSING AUTHORITY**

ARVIND KUKREJI

सहायक औषधि नियंत्रक (भारत)

Assistant Drugs Controller (India)

स्वास्थ्य सेवा Seal/Stamp

Directorate General of Health Services  
F.D.A. Bhawan, Kola Road  
New Delhi-110 002

**Conditions of Licence**

1. A photocopy of licence shall be displayed in a prominent place in a part of the premises, and the original licence shall be produced, whenever required.
2. Each batch of drug imported into India shall be accompanied with a detailed batch test report and a batch release certificate, duly signed and authenticated by the manufacturer with date of testing, date of release and date of forwarding such reports. The imported batch of each drug shall be subjected to examination and testing as the licensing authority deems fit prior to its marketing.
3. The licensee shall be responsible for the business activities of the manufacturer in India along with the registration holder and his authorised agent.
4. The licensee shall inform the licensing authority forthwith in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the licensing authority in the name of the firm with the changed constitution";