

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  
07 APR 2011

M/s. Glaxo Smith Kline Pharmaceuticals Ltd.  
S.NO. 14/4, Godown NO.1 & 2, Village Yavai, Nr. Water Filtration Plant,  
Dist. Thane 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. RA/217/2011 Dated 22.03.2011 received by this office vide diary no. 13903 dt. 24.03.2011, I enclose licence(s) Nos. FF-308-5088 dated 07 APR 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, 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. 6-4/FF/71/04-DC (Re-Registration-2010)

Copy together with copy of Licence No. FF-308-5088 dated 07 APR 2011

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 FF-308-5088

Date

07 APR 2011

1. M/S. Glaxo Smith Kline Pharmaceuticals Ltd. S.NO. 14/4, Godown NO.1 & 2, Village Yavai, Nr. Water Filtration Plant, Dist. Thane Bhiwandi is hereby licensed into India during the period for which this licence is in force, the drugs specified below, manufactured By M/s. Glaxo Wellcome Production, 1 Rue De 1 Abbaye-76960, Notre Dame De Bondeville, France 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 29/03/2011 to 31/12/2013 unless it is sooner suspended or cancelled under the said rules.

Names of drugs to be imported

1. **Nadroparin Calcium Injection: Fraxiparine Injection**  
(Prefilled Syringes-0.2ml, 0.3ml, 0.4ml, 0.6ml, 0.8ml, 1.0ml=9500 IU Axa/ml), Fraxiparine Injection (Multidose Vials-5ml, 15ml=9500 IU Axa/ml), Fraxodi Injection (Prefilled Syringes-0.6ml, 0.8ml, 1.0ml = 19000 IUAXa/ML)

2. **Fondaparinux Sodium Injection:- Arixtra Injection**  
(Prefilled Syringes-2.5mg/0.5ml), Arixtra Injection (12.5mg/ml in Prefilled Syringes of 0.4ml, 0.6ml & 0.8ml)  
Item (Two) Only

Place: New Delhi

Date: 07 APR 2011

LICENSING AUTHORITY

अरविन्द कुक्रेती  
ARVIND KUKRETY

सहायक-औषधि नियंत्रक (भारत)  
Assistant Drugs Controller (India)

स्वास्थ्य सेवा महानिदेशालय  
Directorate 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";