

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

22 MAR 2011

M/s. Themis medicare limited
69/A, G.I.D.C. Industrial estate, Vapi,
Dist-Valsad-396195

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 16/03/2011 received by this office vide ~~no. 12517~~ dt. 16/03/2011, I enclose licence(s) Nos. BD-878-18779 dated 22 MAR 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,


Assistant Drug Controller (India)

No. 6-3/BD/23/10-DC

Copy together with copy of Licence No. BD-878-18779 dated 22 MAR 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 BD-878-18779

Date 22 MAR 2011

1. M/S. Themis medicare limited 69/A, G.I.D.C. Industrial estate, Vapi, Dist-
Valsad-396195 is hereby licensed into India during the period for which this licence
is in force, the drugs specified below, manufactured By M/s. Ningxia Duowei
Pharmaceutical Co. Ltd. Wangyuan Economic Zone, Yongning County,
Yinchuan, Ningxia 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 17/03/2011 to 31/10/2011 unless it is sooner
suspended or cancelled under the said rules.

Names of drugs to be imported

Cyanocobalamin IP (Vitamin B12)

Item (One) Only

Place: New Delhi

Date: 22 MAR 2011

OFFICE COPY

LICENSING AUTHORITY

अरविंद कुक्रेती

ARVIND KUKRETI

सहायक औषधि नियंत्रक (आर.डी.ओ.)

Assistant Drugs Controller (India)

स्वास्थ्य सेवा मंत्रालय

Directorate General of Health Services

F.D.A. Bhawan, Kolla Road

New Delhi - 110 012

Conditions of Licence

1. A photocopy of licence shall be displayed in a prominent place in 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;