22

54605/ 31/12/09

P. No. 12-72/2003-DC (Pt-J&J)
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services

FDA Bhawan, New Delhi-02
Dated 7/7/X

To,

M/s. Johnson and Johnson Limited,
30, Forjett Street,
Mumbai- 400036

Sub: **Paliperidone Palmitate Prolonged Release Suspension for Injection.**

Ref: Your letter dated 6/04/2010.

Sir,

Please find enclosed herewith permission No. **Import-573/2010 dt.** 7/7/X in **Form 45** under Drugs & Cosmetics Acts & Rules thereunder.

Please acknowledge receipt of the same.

Yours faithfully

(Dr. Surinder Singh)
Drugs Controller General (India)

To

The Commissioner,
Food and Drugs Administration,Opp.
R.B.I. Building, Bandra,
Mumbai- 400051 (Maharashtra)

54605/ 31/12/09

F.No. 12-72/2003-DC (Pt-J&J)
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
FDA Bhawan, New Delhi – 110 002(India)

Form-45

(See rules 122-A, 122-D and 122-DA)
Permission to Import finished formulation of the new drug

****

Number of the permission and date of issue **Import-573/2010**

M/s Johnson and Johnson Limited, 30, Forjett Street, Mumbai- 400036. (address) is hereby permitted to import the following new drug formulation under rule 122-A/122-D/ 122-DA of the Drugs and Cosmetics Rules-1945.

(1) **Name of the drug** : **Paliperidone Palmitate Prolonged Release Suspension for Injection. (M/s Janssen Pharmaceutica NV, Beerse, Belgium.)**

(2) **Dosage Form** : **Prolonged Release Suspension for Injection (Pre- filled Syringes)**

(3) **Composition** : **Each Prefilled syringe of 0.25ml /0.5ml/ 0.75ml/ 1ml/ 1.5ml/ contains:- Paliperidone Palmitate equiv. to Paliperidone.....25/50/75/100 and 150mg.**

(4) **Indication** : **For the acute and maintenance treatment of Schizophrenia in adults.**

Date: 7/7/x

Signature:

(Dr. Surinder Singh)
Drugs Controller General (India)
(Name & Designation of Licensing Authority)

Conditions for Grant of Approval / Permission.

1. The formulation shall conform to the specifications approved by the Licensing Authority.

2. The proper name of the drug shall be printed or written in indelible ink and shall appear in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.

3. The label of the innermost container of the drug and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which shall not be less than 1 mm in width and without disturbing the other conditions printed on the label to depict it as prescription drug.

4. The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning:

   "WARNING : To be sold by retail on the prescription of Psychiatrist only."

5. Post marketing surveillance study shall be conducted during initial period of two years of marketing of the new drug formulation, after getting the protocol and the names of the investigator duly approved by the Licensing Authority.

6. All reported adverse reactions related to the drug shall be intimated to the Drugs Controller, India and Licensing Authority and regulatory action resulting from their review should be complied with.

7. No claims except those mentioned above shall be made for the drug without the prior approval of the Licensing Authority.

8. Specimen of the carton, labels, package insert that will be adopted for marketing the drug in the country shall be got approved from the Licensing Authority before the drug is marketed.

9. Each consignment of imported drug shall be accompanied by test/analysis report.

The above Import and Marketing permission is subject to condition that samples of Paliperidone Palmitate Prolonged Release Suspension for Injection 25/50/75/100 and 150mg shall be tested at CDL, Kolkata prior to market in the country.