F.No.12-54/16-DC (Pt-B)
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
FDA Bhawan, New Delhi – 110 002 (India)

Dated: 25.05.17

To
M/s. Mylan Laboratories Limited,
F-4 & F-12, Malegaon MIDC,
Sinnar, Nashik, 422 113,
Maharashtra, India

Sub: FDC of Sofosbuvir 400 mg + Velpatasvir 100 mg Tablets- regarding

Ref: Your letter dated 05.05.2017

Sir,

Please find enclosed herewith permission no. **MF-ND-113/2017** dt. 25.05.17 in **Form-46** under Drugs & Cosmetics Act & Rules there under.

Please acknowledge receipt of the same.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:-

1. **The Commissioner,**
   Food and Drugs Administration (FDA),
   Maharashtra, 341, Bandra Kulra Complex,
   Opp. RBI Building, Bandra (East) Mumbai-400 051.
2. **DDC (I), CDSCO, West Zone.**

Diary No. 052317/ Date of application: 16.11.2016

सत्यमेव जयते

F.No.12-54/16-DC (Pt-B)
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
FDA Bhawan, New Delhi – 110 002 (India)

Form 46

(See rules 122B, 122D, 122DA)

PERMISSION/APPROVAL FOR MANUFACTURE OF NEW DRUG FORMULATION

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Number of the permission and date of issue **MF- ND-113/2017**

M/s. Mylan Laboratories Limited, F-4 & F-12, Malegaon MIDC, Sinnar, Nashik, 422 113, Maharashtra, India is hereby granted permission/approval to manufacture the following new drug formulation under rule ~~122B~~/122D/~~122DA~~ of the Drugs and Cosmetics Rules-1945, namely:

(1)	**Name of the formulation:**	**Sofosbuvir (400 mg) + Velpatasvir (100 mg) Tablet.**
(2)	**Dosage Form:**	**Film Coated Tablet**
(3)	**Composition:**	**Each film coated tablet contains:** **Sofosbuvir ..... 400 mg** **Velpatasvir .....100 mg**
(4)	**Indications:**	**"For the treatment of adult patients with chronic Hepatitis C Virus, Genotype 1,2,3, 4, 5 or 6 infection:** **.without cirrhosis or with compensated cirrhosis** **.with decompensated cirrhosis for use in combination with Ribavirin.**

Dated: 25.05.17

Signature: _____

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

CENTRAL DRUGS STANDARD CONTROL ORGANISATION CDSCO CDSCO MINISTRY OF HEALTH GOVERNMENT OF INDIA

Condition 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 cover 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 of the left side running throughout the body of the label which shall not be less than 1mm in width and without disturbing the other conditions printed on the label to depict it is prescription drug.
4. The label of 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 "Hepatologist only".

5. As post marketing surveillance, the applicant shall have a Pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drug manufactured or marketed by the applicant in the country.
   a) The system shall be managed by qualified and trained personnel and the officer in-charge of collection and processing of data shall be a medical officer or a pharmacist trained in collection and analysis of adverse drug reaction reports.
   b) Subsequent to approval of the product, new drug shall be closely monitored for its clinical safety once it is marketed.
   c) The applicant shall submit Periodic Safety Update Reports every six months for the first two years. For subsequent two years, the Periodic Safety Update Reports shall be submitted annually.
6. All reported adverse reaction 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 dru in the country shall be got approved from the Licensing Authority before the drug marketed.
9. **The firm shall conduct a Phase-IV clinical trial on statistically significant number patients in the country. Accordingly protocol shall be submitted within thre months to the office of DCG (I).**
10. **The data generated from the ongoing phase III clinical trial shall be submitte before the committee after completion.**
11. **The Firm shall submit complete stability study data as per Appendix-IX of Schedule Y Drugs & Cosmetics Rules, 1945 before marketing the drug.**