11283/05.05.17

File No. 4-140/2017-DC (PSC-P&C)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

Tele. No. : 011-23236965
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FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 01 JUN 2017

To,
M/s. Pure and Cure Healthcare Pvt Ltd.,
26A-30 Sector-8A, IIE, Ranipur,
Haridwar-249403

Subject: **Manufacture and market FDC of Gliclazide BP 80mg/40mg + Metformin HCL 500mg/500mg uncoated tablets-regarding.**

Reference: **Your application dated 05.05.2017 in Form 44.**

Sir,

All the State Drug Controllers vide this office letter no. 4-01/2013-DC (Misc. 13-PSC) dated 15.01.2013 were requested to ask the concerned manufactures to prove safety and efficacy of such FDCs before DCG (I), the Licensing Authority under Rule 21(b) of the Drugs and Cosmetics Rules, 1945 as amended from time to time within 18 months, in case these are being manufactured without such approval on the basis of licenses granted by State Licensing Authority.

Accordingly, FDC of **Gliclazide BP 80mg/40mg + Metformin HCL 500mg/500mg uncoated tablets** for other applicant was examined and considered for granting approval for manufacturing and marketing.

Your application has been examined as per the procedure laid down and based on such examination; this Directorate has no objection for manufacturing and marketing of FDC of **Gliclazide BP 80mg/40mg + Metformin HCL 500mg/500mg uncoated tablets.** This approval is issued with the following conditions:-

1. The formulation shall conform to the standards and requirements of Drugs and Cosmetics Act and Rules thereunder.
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 on the left side running throughout the body of the label which shall not be less than 1mm in width and without disturbing other conditions printed on the label to clearly show that it is a 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:

   i. **"WARNING: To be sold by retail on the prescription of R.M.P. only".**

5. As Post marketing surveillance, 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 reactions related to the drug shall be intimated to the DCG(I) and Licensing Authority; and regulatory action resulting from their review should be complied with.

Yours faithfully,

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

Copy to:-

State Drugs Controller, **Uttarakhand**-with a request to issue permission of subject FDC as per procedure laid down vide notice dated 16.03.2017, if other conditions of License under Drugs and Cosmetics Rules, which needs to be verified by you, are found to have been fulfilled. You are requested to verify the quality of subject patent and proprietary drug (FDC) applied by **M/s. Pure and Cure Healthcare Pvt Ltd., Plot no. 26A-30 Sector-8A, IIE, Ranipur, Haridwar-249403, Uttarakhand** as per Drugs and Cosmetics Rules, 1945 before grant of license.