Z-28020/247/2015-DC Directorate General of Health Services Office of DCG (I) (RTI CELL)

FDA Bhawan, New Delhi. Dated:

To,

Sh. Prashant Reddy T. C/o Advocate Harsh Parashar, Lex One Partners, E-19, LGF, Jungpura Extention, New Delhi - 110 014

Sub: Information under RTI Act, 2005 - Regarding.

Sir,

Please refer to your letter no. Nil dated 06-04-2015 received in this office on dated 10-04-2015 regarding information under RTI Act, 2005.

The point wise information is placed as below:

POINT NO. A

For drugs meant for export to other countries approval for marketing in their country are granted by the regulatory authority of the importing country. Health Canada issued permission for marketing the drugs in Canada after evaluation of the facilities and verifying compliance as per the requirement laid down by it. There is no agreement on requirement that CDSCO communicates with Health Canada when a ban is imposed on products manufactured by the firms registered with Health Canada.

POINT NO.B

Licenses are issued by the State Licensing Authorities and inspections are conducted periodically. CDSCO headquarters has not conducted any inspection with respect to the alleged ban imposed by Health Canada.

Yours Faithfully,

(Sunil Kulshrestha) Central Public Information Officer

Address of first appellate authority is as below:

The Drugs Controller General (India)

FDA Bhawan, Opp. Mata Sundri College,

Kotla Road, New Delhi – 110002.