F.No. 20(123)/2016/DP/NPPA/Div.II भारत सरकार

Government of India रसायन एवं छर्वरक मंत्रालय

Ministry of Chemical and Fetilizers

Department of Pharmaceuticals राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण National Pharmaceutical Pricing Authority

> 3rd/5th Floor, YMCA Cultural Centre Building 1, Jai Singh Road, New Delhi-8 Dated 18-11-2016

To,

The Managing Director/ CEO, M/s Fresenius Kabi India Pvt. Ltd. 301, 3rd Floor Wagh Apartments 3 Park Road, Vile Parle (East), Mumbai 400 057.

Subject: Review Order No 31015/12/2016-PI.I dated 04.8.2016 in respect of Gemcitabine Hydrochloride Injection(1ml) and Filgrastim Injection (1ml) under 11(3).

Sir.

With reference to above, I am directed to refer to the review order cited above and request you to provide the following information in respect of the subject formulations: -

- (i) whether there is any distortion noticed in the Ceiling prices of the mentioned formulations on account of the pack-size, which may perhaps cause some of the packs to be non-remunerative or unviable compared to other pack-sizes/ single use — multi use.
- (ii) whether there is any special feature on any product which makes this formulation different from others on account of therapeutic benefit, and the rationale for the separate ceiling price.
- (iii) your data/information in respect of overcharging notice(s) issued by NPPA, if any, for the above mentioned formulations.
- You are therefore, requested to furnish the above details as soon as possible along with all
 necessary documentary evidence in support of your contention enable to NPPA to take further
 necessary action.

(AK Khurana) Director (Pricing)

Copy to: (for information & necessary action please)

(i) Apex Pharma Organisations viz. IDMA, OPPI, CII, IPA, AISSPMA, FICCI & FOPE.

(ii) Other manufacturers/ marketing companies for the subject formulation(s).