Most Immediate

FTS No.100460/2013-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 11th June, 2013

To.

The Drugs Controller General (I),
FDA Bhawan, Kotla Road,
Near Bal Bhawan, New Delhi.

DCG(I)

Subject:- Manufacture and distribution of certain adulterated drugs made at two Ranbaxy's manufacturing facilities in India – Regarding.

Sir,

I am directed to say that it has come to the notice of the Ministry of Health & Family Welfare that Ranbaxy USA Inc. has pleaded guilty in the USA to charges relating to the manufacture and distribution of certain adulterated drugs made at two of Ranbaxy's manufacturing facilities in India and that the Ranbaxy has been imposed a total of $500 million as fine.

2. In this connection, it is requested that necessary inspections may be conducted, as per the provisions of the Drugs & Cosmetics Act and Rules, to review the GMP compliance of the above referred two manufacturing facilities of Ranbaxy in India as well as to ascertain the safety, quality and efficacy of drugs manufactured for the domestic market in these facilities, particularly during the period in question.

3. This should be in addition to routine inspection and sampling of products being manufactured by various firms, including Ranbaxy.

This issues with the approval of the competent authority.

Yours faithfully

(Shailendra Kumar)
Director
23061656