Z-28020/344/2015-DC
Directorate General of Health Services
Office of DCG (I)
(RTI CELL)

FDA Bhawan, New Delhi.
Dated: 1/7/15

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 07-04-2015 received in this RTI cell on dated 28-05-2015 regarding information under RTI Act, 2005.

The point wise information in respect of 2 & 3 is place as below:

POINT NO. 2

Copy of letter enclosed here for refrence.

POINT NO. 3

The information sought by the applicant regarding question no. 3 has been considered to be exempted for disclosure under section 8(1) (h) of RTI Act being providing of such information would impede the process of investigation carried out by various State Licencing Authorities (SLAs). Further, there information also considered to be trade secret/commercial confidence in nature and exempt for disclosure under section 8(1) (d) of RTI Act.

Yours Faithfully,

(Sunil Kulshrestha)
Central Public Information Officer

Copy to:
The Under Secretary/CPIO, DFQC Section, Ministry and Family Welfare, Nirman Bhawan, New Delhi - 110011

Address of first appellate authority is as below:
The Drugs Controller General (India)
FDA Bhawan, Opp. Mata Sundri College,
Kotla Road, New Delhi – 110002.

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