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Z-28020/541/2017-DC
Directorate General of Health Services
Office of DCG (I)
(RTI CELL)

FDA Bhawan, Kotla Road,
New Delhi
Date: 20/12/17

To,

Sh. UmeshChandra Chandu Barkur,
A-15, Neeta Apartments,
Chaphhekar Bandhu Marg,
Mulund East,
Mumbai-400081

Sub: Information under RTI Act, 2005 - Reg.

Sir,

Please refer to your RTI application no. DTGHS/R/2017/90070 dated 20.11.2017 received in this office on dated 29.11.2017 regarding information under RTI Act, 2005.

Reply Point no. (a) to (g): As per Schedule M of Drug and Cosmetics Rules, all complaints thereof concerning product quality shall be carefully reviewed and recorded according to written procedures by the manufacturing companies. Each complaint shall be investigated/evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained. There shall be written procedures describing the action to be taken, recall to be made of the defective product. Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority.

It is further to inform as stated by you that FDA Maharashtra has already taken action and the Drug Inspector had seized drugs valued at rupees five lakhs and eight thousand for sale without valid license as required under the Drugs and Cosmetics Act, 1940. A case was also filed with the Addl. Chief Metropolitan Magistrate 15th Court, Mazgaon, Mumbai in October 2016 on your compliant. In this regard you are requested to approach the FDA Maharashtra for the requisite information under RTI Act, 2005.

For Reply Point no. (k): Your RTI application is being transferred u/s 6 (3) of the RTI Act, 2005 to CPIO, NPPA and Medical Council of India for providing available information, if any.

Yours Faithfully,

(Jayant Kumar)
Central Public Information Officer

Copy to:-

1. Sh. Sunitha Bhatia, Section Officer, MoH&FW, Nirman Bhawan, New Delhi- 110011 in reference to F.No. Z.17025/636/2017-RTI CELL dtd. 23.12.2017.
2. The CPIO National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, 5th / 3rd Floor, YMCA Cultural Centre Builing, 1, Jai Singh Road, New Dlehi-110001 with request to provide available information.
3. The CPIO, Medical Council of India, Pocket- 14, Sector- 8, Dwaraka, New Delhi-110077 with request to provide available information.

Address of first appellate authority is as below:

Sh. A. K. Pradhan,
Deputy Drugs Controller (India),
FDA Bhawan, Opp. Mata Sundri College,
Kotla Road, New Delhi -- 110002

Drugs and Cosmetics Rules

Schedule M

27. Product Recalls. –

27.1 A prompt and effective product recall system of defective products shall be devised for timely information of all concerned stockists, wholesalers, suppliers, upto the retail level within the shortest period. The licensee may make use of both print and electronic media in this regard.

27.2. There shall be an established written procedure in the form of Standard Operating Procedure for effective recall of products distributed by the licensee. Recall operations shall be capable of being initiated promptly so as to effectively reach at the level of each distribution channel.

27.3 The distribution records shall be readily made available to the persons designated for recalls.

27.4 The designated person shall record a final report issued, including reconciliation between the delivered and the recovered quantities of the products.

27.5 The effectiveness of the arrangements for recalls shall be evaluated from time to time.

27.6 The recalled products shall be stored separately in a secured segregated area pending final decision on them.

28. Complaints and Adverse Reactions.

28.1 All complaints thereof concerning product quality shall be carefully reviewed and recorded according to written procedures. Each complaint shall be investigated /evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained.

28.2. Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority.

28.3 There shall be written procedure describing the action to be taken, recall to be made of the defective product.