

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:4377

ANSWERED ON:20.12.2012

SEIZURE OF DRUGS BY U.S. FOOD AND DRUG ADMINISTRATION

Dhurve Jyoti

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the U.S. Food and Drug Administration seized the entire stock of drugs manufactured by Caraco Pharmaceuticals Laboratory, a subsidiary of Sun Pharma on repeated violations of standards laid down for manufacturing drugs;

(b) if so, the details in this regard and its likely impact thereof; and

(c) the steps being taken by the Government to resolve this issue with USFDA and to resume manufacturing operation by observing good manufacturing practices by all pharmaceutical companies in the country ?

Answer

MINISTER OF STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) & (b) The Department has no information on the issue as it relates to a subsidiary of Indian Company located in USA. However, Pharmaceutical Export Promotion Council (Pharmexcil) has informed that from the Press Release issued by Sun Pharmaceuticals on 28th August, 2012, it appears that USFDA had issued warning letters to Caraco Pharmaceutical Laboratories (located in USA) for deviation in good manufacturing practices in their plants. After corrective steps taken by M/s Caraco Pharmaceuticals Laboratories, USFDA had permitted to resume two products and Caraco is in the process of taking corrective measures for rest of the products. Regarding the extent of impact of these warning letters to Caraco Pharmaceuticals/ Sun Pharmaceuticals, no information is available.

(c) In view of (a) & (b) above, does not arise.