

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

UNSTARRED QUESTION NO:3776

ANSWERED ON:30.07.2009

SEIZURE OF DRUGS BY USFDA

Gaikwad Shri Eknath Mahadeo; Patasani Dr. (Prof.) Prasanna Kumar; Ray Shri Rudramadhab ; Yaskhi Shri Madhu Goud

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

(a) whether the US Food and Drugs Administration (USFDA) has seized the entire stocks of Drugs manufactured by Caraco Pharmaceutical Laboratories, a subsidiary of Sun Pharma citing repeated violations of manufacturing norms;

(b) if so, the details thereof;

(c) the likely impact thereof on Sun Pharma; and

(d) the steps being taken by the Government to resolve the issue with USFDA and efforts being made to return to good manufacturing practices compliance?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) to (d) M/s Sun Pharmaceutical Industries Ltd. has informed that M/s Caraco Pharmaceutical Laboratories has reported that on 25-06-2009 U.S. Food and Drug Administration (FDA), seized drug products manufactured in Caraco's Michigan facilities in Detroit, Farmington Hills and Wixom on account of unresolved violations of eGMP requirements. M/s Caraco has informed that they are working with the FDA to resolve the concerns as effectively and expeditiously as possible. M/s Sun Pharmaceutical Industries Ltd. has clarified that neither Sun Pharma nor Caraco have approached or made any representation to the Government for any kind of assistance for resolution of this problem.