

GOVERNMENT OF INDIA  
MINISTRY OF COMMERCE & INDUSTRY  
(DEPARTMENT OF COMMERCE)

LOK SABHA  
UNSTARRED QUESTION NO. 1185  
TO BE ANSWERED ON 02<sup>nd</sup> MAY, 2016

**REJECTION OF MADE-IN-INDIA PRODUCTS BY USFDA**

**1185. SHRI BHAGWANTH KHUBA:**

Will the Minister of **COMMERCE & INDUSTRY** (वाणिज्य एवं उद्योग मंत्री ) be pleased to state:

- (a) whether the US Food and Drug Administration (USFDA) has rejected a large number of Made-in-India products during the last five years;
- (b) if so, the details thereof;
- (c) whether the production of these products was below standard quality; and
- (d) if so, the details thereof along with the action taken by the Government in this regard?

**ANSWER**

वाणिज्य एवं उद्योग राज्य मंत्री (श्रीमती निर्मला सीतारमण) (स्वतंत्र प्रभार)

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY  
(INDEPENDENT CHARGE)  
(SMT. NIRMALA SITHARAMAN)

(a) & (b) According to Import Refusal Report data available on the US FDA website (<http://www.accessdata.fda.gov/scripts/importrefusals/>), 12,012 refusals of Indian products were recorded from January, 2011 to March, 2016.

(c) & (d) The reasons given for the refusals include misbranding, adulteration, packaging, labelling, pesticides, unapproved products, etc. Among the steps taken by the Government include tightening labelling rules and making it mandatory for companies to clearly mention the dates of manufacturing, best before use and expiry dates, improving pre-export inspection, greater emphasis on standards through sensitization of exporters for compliance of regulatory issues through export promotion agencies and also taking up the issues at bilateral trade forums, wherever appropriate.

\*\*\*\*\*