(a) whether it is a fact that several kinds of impediments have come across in the implementation of the decision to promote more foreign capital investment in retail market in the country;

(b) if so, the details of these impediments;

(c) whether Government has taken any steps to remove these impediments; and

(d) if so, the details thereof and by when Government aims to remove these impediments?

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (DR. S. JAGATHRAKSHAKAN): (a) No, Sir. Government has recently announced the following decisions:—

(i) Amendment of certain conditions relating to FDI, up to 100%, in single brand retail trading, vide Department of Industrial Policy and Promotion's Press Note No. 4 (2012 Series) dated 20.9.2012

(ii) Permitting FDI, up to 51%, in multi-brand retail trading, subject to specified conditions, vide Department of Industrial Policy & Promotion's Press Note No. 5 (2012 Series) dated 20.9.2012

(b) to (d) Do not arise.

Payment of fee for selling generic drugs in US

2799. SHRI A. ELAVARASAN: Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether all generic pharmaceutical companies including Ranbaxy, Cipla, Dr. Reddy etc. have to pay a fee to the US Drug regulator when they seek its permission to sell their products there;

(b) if so, the details thereof;

(c) whether a Generic Drug User Fee Act is on the way to enable the US Food and Drug Administration (FDA) to levy a user fee on each generic application filed for approval;

(d) whether the move is expected to have a financial impact on generic drug makers; and

(e) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (SHRIMATI D. PURANDESWARI): (a) to (c) According to the Generic Drug User Fee Amendments of 2012 (GDUFA) dated 9.7.2012 of US Government, any company interested in supplying drugs and pharmaceuticals have to pay the prescribed fee to the Food and Drug Administration (FDA) with effect from 1st October, 2012 for registering their products in USA.

(d) and (e) There will be financial impact on generic drug exports to USA as the exporters are now required to pay about Rs. 30.00 lakhs for registration of each Abbreviated New Drug Application (ANDA) and about Rs. 12.00 lakhs for filing of Drug Master File (DMF).

Seizure of chinese drugs with Made in India labels

2800. DR. V. MAITREYAN: Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether some consignments of pharmaceuticals and drugs exported to Africa from China were seized and labels of made in India were found pasted on them during the last three years;

(b) if so, the details thereof;

(c) the reaction of Government along with the steps taken/being taken by Government in this regard;

(d) whether Government has taken up this matter with the Chinese authorities; and

(e) if so, the reaction of the Chinese authorities in the matter?

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (SHRIMATI D. PURANDESWARI): (a) and (b) During June, 2009, Government of India's attention was drawn to the press release issued by NAFDAC, Nigerian Government Drug Regulatory Authority, about detention and seizure of a large consignment of fake anti-malarial generic pharmaceuticals labelled 'Made in India' but produced in China.

NAFDAC once again intercepted a large consignment, of counterfeit medicines flown in from China in Nigeria in June, 2010. The consignment was of 'Ciprotab', a product of an Indian company, which was counterfeited by a Chinese company.