THE MINISTER OF STATE IN THE DEPARTMENT OF RAILWAYS (SHRI MADHAVRAO SCINDIA) : (a) : Sufficient facilities are available at Ernakulam Goods Station to meet the existing traffic requirements. At present there is no proposal for providing additional facilities at this station.

(b) No. Sir.

(c) No; Sir.

(d) Does not arise.

Allotment of Book stalls to Unemployed Graduates at Railway Stations

5085. SHRI SODE RAMAIAH : Will the Minister of TRANSPORT be pleased to state :

(a) what alternative arrangements have been made during the notice period of three months and after to continue book stall facility at those stations which were previously held by Gulab Singh & Sons ;

(b) how many unemployed graduates were awarded book stalls on those stations through normal procedure and if none, reasons thereof ; and

(c) how many applications from unemployed graduates were received in response to railway advertisements for allotment of book stalls on those stations which were previously held by M/s. Gulab Singh & Sons and also finalised on merits ?

THE MINISTER OF STATE IN THE DEPARTMENT OF RAILWAYS (SHRI MADHAVRAO SCINDIA) : (a) to (c) M/s. Gulab Singh and Sons had obtained a stay order from the High Court of Delhi before expiry of the three months notice period, and are still operating bookstall at various stations under Court's orders. The case is sub-judice. Action regarding finalisation of award of contracts, based on the applications received, will be taken only after vacation of the stay order.

Guidelines for Clearance of New Drugs and New Combination of Drugs

5088. SHRI TARIQ ANWAR : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether Government have laid down any guidelines for clearance of new drugs and new combination of drugs in the country ; and

(b) if so, the details thereof ?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR) : (a) Yes, Sir.

(b) The essential components of the Guidelines are as follows :—

(i) The Various Rules of the Drugs and Cosmetics Act under which import or manufacture of a new drug is granted by the Drugs Controller (India), who under Rule 21 of the Drugs and Cosmetics Rules is the licensing authority to approve a new drug.

(ii) The various situations under which a new drug is required to be clinically tried in India notwithstanding whether such a drug is already approved in other countries.

(iii) The various formalities and the data that are required to be submitted to the concerned authority for obtaining permission to carry out different phases of clinical trials in India.

(iv) The responsibilities of sponsor/investigator involved in clinical evaluation of a new drug in the country.

(v) Data required to be submitted with an application for obtaining permission to carry out clinical trial in the country which includes