availability of funds. About 60 Km Track renewal works have been done in the yards and six number washing lines have been constructed in Delhi area, during the last five years.

Approval of dangerous projects and industries

†*142. SHRIMATI KUM KUMRAI: Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) whether it is a fact that during the last two years Government have given clearance to such type of projects and industries which are very dangerous from environmental point of view; and

(b) if so, the details thereof?

THE MINISTER OF ENVIRONMENT AND FORESTS (SHRI A. RAJA): (a) and (b) No, Sir. The Central Government has enacted the Environment (Protection) Act (EPA), 1986 and framed Rules thereunder for the protection and the improvement of environment and prevention of hazards to human beings, other living creatures, plants and property. Ministry grants environmental clearance to 32 categories of development projects and industries covered under the Environmental Impact Assessment Notification, 1994 issued under the EPA, 1986 after assessing the Environmental Impact Assessment and Risk Analysis Reports and subject to compliance to stringent environmental and risk mitigation measures.

Clinical trials by multinational companies

*143. SHRIMATI BRINDA KARAT: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what is Government's policy regarding clinical trials being conducted by multinational companies in the country;

(b) the steps taken by Government for regulating such clinical trials;

(c) whether Government have any mechanism to monitor/regulate such medical trials;

(d) if so, the details thereof; and

(e) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS) :(a) to (e) Regulations for conducting clinical trial in the country including by multinational companies are prescribed under Rule-122 DA-122-E and Schedule-Y to the Rules. The Rules provide specific application from and relevant document requirements for seeking permission

†Original notice of the question was received in Hindi.

to conduct clinical trials. The data/documents are evaluated in consultation with subject experts.

Permission to conduct phase-l trial, including first time use in human beings, is presently not granted for new drugs developed outside the country. For drugs developed outside the country — multicentric clinical trials at phase-ll and III stage are permitted after similar trial protocol has been approved by regulatory authorities of the countries where such drugs have been invented. Permission to conduct trials on new drugs invented outside the country takes into consideration the permissions granted by stringent ICH countries (viz. USA, EU, Japan, etc.)

Schedule-Y, which prescribes requirements for permission to conduct clinical trials was introduced in 1988. The amended version, notified in February, 2005, after extensive revision, lays down stringent and specific procedures that need to be followed by Sponsors, Investigators as well as Ethics committees. The amendment lays special emphasis on the modalities for obtaining informed consent from clinical trial subjects, and the language to be used for consent forms have also been prescribed. The Rules also require that prior approval of Institutional Ethics Committee has to be obtained before undertaking any clinical trial in the country. Membership criteria as well as conduct of Ethics Committee meetings have also been prescribed in the amendment. The revision has been made in consultation with experts including experts from ICMR, with the basic intent of making regulations in line with contemporary global standards for clinical trials.

The Government has brought out detailed guidelines on Good Clinical Practices (GCP), which are also required to be followed during conduct of a trial. These are also at par with very stringent international practices.

The Ministry has conducted several training programs with the support of WHO to make clinical research stakeholders aware of the new regulations and to impart them training on complying with the highest standards.

While it has been made mandatory that Sponsors conduct periodic monitoring and audits of the studies, a process for conducing regulatory inspections has also been initiated. More than 30 subject experts from various medical institutions and Central Drugs Standard Control Organization, have undergone a training workshop which was held in coordination with Department of Pharmacology, All India Institute of Medical

Sciences, New Delhi, to equip them to carry out regulatory inspections of clinical trials.

Introduction of Trains running 100 Km. per Hour

*144. SHRIMATI VANGA GEETHA: Will the Minister of RAILWAYS be pleased to state:

(a)whether Government have any proposal to introduce trains in Andhra Pradesh which run at 100 Km. per hour;

(b)if so, whether Government have identified any routes for this purpose;

(c)if so, the details thereof;

(d)whether Government have conducted any trial before introducing these trains;

(e)if so, the details thereof;

(f) the time-frame set to introduce these trains; and

(g)the details of extra expenditure likely to be incurred for this purpose?

THE MINISTER OF RAILWAYS (SHRI LALU PRASAD): (a) to (c) Railways are already running trains at 100 kmph and above in Andhra Pradesh on the following sections:

1. Balharshah-Vijayawada-Chennai
2. Vijayawada-Visakhapatnam-lchchapuram
3. Wadi-Secunderabad-Kazipet
4. Wadi-Guntakal-Arakkonam
5. Gooty-Dharmavaram-Bangalore
6. Gudur-Renigunta-Tirupati
7. Pagidipalli-Nadikude-Guntur
8. Guntur-Tenali
9. Guntur-Dhone
10. Secunderabad-Dhone-Guntakal
11. Vijayawada-Gudivada
12. Guntakal-Bellary
13. Samalkot-Kakinda Port
14. Bangalore-Jolarpettai