

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:2128
ANSWERED ON:07.12.2005
CLEARANCE TO NEW DRUG APPLICATIONS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) the details of the new drug applications received during 2005 both for single ingredient and fixed dose combination including the names of the medicines; the name of the companies and the date of the applications ;
- (b) whether approval has been granted to each of these applications ; and
- (c) if not the details of pending applications alongwith the reasons therefor?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (c): As per records, the new drug applications received during 2005 both for single ingredient and fixed dose combinations are about 1074.

Approval of new drugs is a continuous process. The details of drugs including fixed doses combinations approved for the first time in the country is available at website www.cdsc.nic.in. Approvals for subsequent applications are being granted simultaneously on the basis of Bio Equivalence (B/E) study reports and quality control reports etc. Rest of the applications are under various stages of evaluation such as Bio equivalence studies, clinical studies, expert opinion etc.

The time taken for approval varies from 3 months to 2 years, depending on the nature of the drug and time taken to generate required data.