GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3615
ANSWERED ON:07.08.2002
APPLICATIONS FROM BIO-TECH UNITS
KINJARAPU YERRANNAIDU;SUKENDER REDDY GUTHA

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

a.the number of applications filed by leading Bio-Tech Units in the State of Andhra Pradesh for clearance by the DrugsController-General of India, during each of the last three years;

b.the number of applications cleared by the Drug Controller of India during each of the last three years and the current year;

c.whether the Government of Andhra Pradesh have requested to the Union Government for early clearance of the applications; and

d.if so, the details thereof and the action taken in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a)& (b): 7 applications have been filled in the last 3 years. Status is given in Annexure-I.

(c)& (d): Shri B.P. Achraya, Secretary to Government A.P. through a copy of letter from Hon`ble Chief Minister of Andhra Pradesh addressed to the Hon`ble Union Minister for Health and Family Welfare dated 3.8.2001, requested that suitable instruction be issued to DCG (I) for an early disposal of the pending proposal pertaining to leading biotech units in the States and not to take credence of certain allegations and counter allegations by certain prominent Bio-Tech companies in the State of Andhra Pradesh.

Before approving indigenously manufactured Bio-tech products, the proposal is required to go through various stages like clearance of Recombinant Committee for Genetic Manipulation (under Department of Bio Technology), Validation of test reports by Central Drug Laboratory, Kasauli/Kolkata, Conduction of Clinical Trial, Clearance of Expert Committee constituted by Ministry of Health for r-DNA based Therapeutics, Clearance of Genetic Engineering Approval Committee (GEAC) under Ministry of Environment, verification of manufacturilng facility as per Good Manufacturing Practices (GMP) norms etc.

The office of DCG (I) has approved three proposals pertaining to biotech products after completion of statutory requirements. Permission for conducting clinical trials have been accorded in respect of remaining three applications i.e.
(i) r-streptokinase of M/s Shantha Biotech Pvt. Ltd., Hyderbad,
(ii) r-streptokinase of M/s Bharat Biotech (I) Limited Hyderabad and
(iii)Interferon alpha 2b of M/s. Dr. Reddy`s Lab., Hyderabad

Annexure-I

Year	No. of Applications Received	Year in which required formalities completed	Year in which the proposal cleared by the DCG (I) office
1999	1	Dec 2001	Feb 2002
2000	4	One proposal in the year April 2001 and second proposal in the year March 2002. In the third proposal the clinical trial is being undertaken by the applicant. In the fourth proposal, the report of clinical trial received on 30/6/2002 and GEAC approval is awaited.	One proposal cleared in the year June 2001 and second

proposal cleared in the year
March 2002.

2001 2 In both the proposal, the clinical
trial is being undertaken by the
applicant