File No. Z.17025/10/2005-DC
Directorate General of Health Services
(Drugs Control Section)

Sl No.		
a)	Name of the Section with full address	Drugs Control Section A-548, Nirman Bhawan, New Delhi-110 011.
b)	Telephone Number	23022200 Extension 2668
c)	Channel of Submission of Files	SO(DC)/DDA (D)/ + US(D)/DCG(I)
d)	Name of Coordination Officer/ Information/Administration	DDA (D)
e)	Name of Appellated Authority	DCG(I)
f)	Staff Strength in position	14
g)	Section Officer (DC)	Shri Balbir Singh Sandhu
h)	Assistant	1. Sh. Jai Prakash 2. Smt Anita Handa
i)	Technical Asstt.	1. Sh. S. N. Basu 2. Sh. Aseem Sahu 3. Mrs Kavita Sharma 4. Sh. J. Gangakhedkar 5. Sh. R. K. Rishi 6. Sh. Gaurav Kumar 7. Mrs. Swati Srivastava 8. Dr. Ravikant Sharma 9. Sh. I. S. Hura
j)	UDC	Sh. Umashankar
k)	LDC	Sh. Simanchal Bisoyee
l)	Work Allocation	As per Annexure (Enclosed)

File No. Z.17025/10/2005-DC
Directorate General of Health Services
(Drugs Control Section)

Allocation of Works

Shri Balbir Singh Sandhu	Supervision of entire work of Section
Sh. Jai Prakash	All Administration matter, Audit objection, CSS Scheme, Adjustment of HSCC B ill, Miscellaneous
Smt Anita Handa	GPF, Special Pay, Purchase of different items, Advances , Short-Term, Long-Term, TA/DA, Lagal matter, providing RRT, Electricity Bill, Telephone Charges & maintaining all types of sanctions
Sh. S. N. Basu	As per Annexure (Enclosed)
Sh. Aseem Sahu	As per Annexure (Enclosed)
Mrs Kavita Sharma	As per Annexure (Enclosed)
Sh. J. Gangakhedkar	As per Annexure (Enclosed)
Sh. R. K. Rishi	As per Annexure (Enclosed)
Sh. Gaurav Kumar	As per Annexure (Enclosed)
Mrs. Swati Srivastava	As per Annexure (Enclosed)
Dr. Ravikant Sharma	As per Annexure (Enclosed)
Sh. I. S. Hura	As per Annexure (Enclosed)
Sh. Umashankar	Budget/BE/RE/Plan/Non-Plan & Misc.
Sh. Simanchal Bisoyee	Diary, Despatch & all types of typing

Annexure-1

DUTIES DONE BY ASEEM SAHU

SR. TECHNICAL ASSISTANT (DRUGS CONTROL SECTION)

- Proposals relating to WHO Biennium Budget for various activities/programmes, which have been carried out by this office under project Essential Drugs and other Medicines, maintenance of WHO accounts of all the expenditure incurred in various workshop/programmes etc. conducted during the year.
- Matters relating to construction of Regional Drugs Testing Laboratories at Chandigarh & Hyderabad and related correspondence.
- Matters relating to supply of laboratory equipments to the various states for augmentation of their drugs testing facilities.
- Project of computerization & networking of Central & State Drugs control offices & Labs in the country.
- Scrutiny & processing of applications pertaining to Import of non critical in-vitro diagnostic products which do not require registration formalities as well as import and registration of Medical Devices & Contraceptives.
- Scrutiny & processing of applications pertaining to New Drugs approval.
- Parliament Questions pertaining to the above matters.

Annexure – II

Name : Smt Kavita Sharma
Sr. Technical Asstt
(Drugs Control Section)

Nature of Duties:-

A. New Drugs Approval Work_ To screen the pre-clinical, Clinical and safety data related to new drugs approval in the country as per Drugs and Cosmetics Act, 1940, as per schedule Y;

B. Bioequivalence center approval - To process various applications for the approval of Bioequivalence study center;

C. Processing of Applications using the Available computer software;

D. Preparation of Answers for Parliament Questions;

E. Maintenance of records related to all above in register and computers;

Annexure – III

Gaurav. Kumar, STA
Drug Control Section

Brief description of duties:

1) **Cinical Trial Permission**: To examine the voluminous data including chemical and pharmaceutical information, pharmacological & toxicological data, clinical data of safety and efficacy, clinical trial protocol etc. for the purpose of approval of clinical trials of new drugs.

2) **Import, Marketing And Manufacturing Permission**: To examine chemical and pharmaceutical information, bioavailability / bioequivalance and comparative dissolution study data, stability data, animal toxicity data, clinical and non-clinical data for the purpose of approval of manufacturing / import of new drugs.

3) **Serious Adverse Event (SAE) Reports In Clinical Trial**: Processing of SAE's reported under clinical trial studies and of marketed products.

4) **Custom Duty Exemption**: Processing of application related to Custom Duty Exemption for drugs and formulations.

5) **Court Cases**: Processing of the court cases letters/ notices received from Advocates, Central Govt. Standing Counsel, High Court, Zonal Offices of C.D.S.C.O. etc. To keep current status of all the cases and to visit Delhi High Court whenever required.

6) **Miscellaneous** : Processing of miscellaneous correspondences received from firms, Government & Private Hospitals, State Drug Authority, various Ministries etc.

Annuxure-IV

Work presently done by Sh. RK Rishi, Sr. Scientific Asst. (Pharmacology)

A. Work Pertaining to applications of FDCs:

1. Examining applications for manufacture and market fixed dose combinations (FDCs) in the country:
    a. Preliminary examination.
    b. Review of published literature and regulatory status of FDCs.
    c. Examination of chemical, pharmaceutical, toxicological, clinical study data submitted by the applicant.
    d. Examination of clinical trial and bioequivalence study protocols so as to check their adequacy with regard to technical and regulatory requirements.
    e. Technical examination of clinical trial reports and bioequivalence study reports.
    f. To handle correspondence with experts with regard to essentiality and desirability of the proposed FDC
2. To maintain ***computerized database*** on all information on FDCs such as no. of permissions granted, Clinical trial/bioequivalence NOCs, etc.
3. To assist correspondence with all State Licensing Authorities with regard to irrational combinations floating in the country and drafting letters for taking appropriate regulatory action in this regard.

B. Work Pertaining to applications of INDs:

1. Process applications of New Chemical Entities (NCE) or Investigational New Drug (IND).
2. To correspond with ICMR for comments on the clinical trial protocols and clinical trial reports for INDs going on under various stages.
3. To forward comments of IND subcommittee meeting of ICMR to the concerned firm and convey the response of the firm back to the ICMR.
4. To process permission/NOC of various stages of clinical trial of INDs to the firms.

C. Work Pertaining to National Pharmacovigilance Programme

1. Assist Sh. PK Rastogi ADC(PKR) regarding works pertaining to Pharmacovigilance Programme, who is nodal officer for National Pharmacovigilance Programme
2. Involved in the organization of meetings of NPAC
3. Process files pertaining to appropriate regulatory measures as per the recommendations of NPAC
4. Processing of files and keep records of all official correspondence regarding Pharmacovigilance Programme:
    a. Routine correspondence with all centers
    b. Receive account statements and disbursement of funds to all centers in coordination with consultant CBP (JB Mathur).
    c. Forwarding requests for joining new centers to CDSCO H.Q.
    d. Forwarding requests for removing existing centers that are not functioning up to the prescribed benchmarks to CDSCO H.Q.
    e. To move proposal regarding printing of new ADR forms and other relevant stationary items for programme after taking sanction from CDSCO H.Q.
    f. Clarification about working of the centers as per the protocols/TORs.
5. Organize meetings of Zonal/Regional Centres, preparing reports etc.
6. Manage pvigindia@yahoogroups.com as moderator

D. Misc. Work

1. Preparing answers to Parliament Questions
2. Assisting several meetings called on urgent basis in the office of DCG (I) e.g., meeting on Drug Eluting Stents (DES), subcommittee meeting of DTAB etc.
3. To receive applications and other receipts from various stakeholders at the facilitation counter (5 days per month).
4. Doing photocopies of various letters/documents as and when assigned, other secretarial work including dispatch of letters etc.

Annuxure-V

Brief Resume of Dr Inderjeet Singh Hura

(1) Assisting the Allotment of Narcotic Drug to all the State, Assisting Narcotic drug related correspondence ,Compilation on Information in respect of Form B, Form P, Form B/P, Form C, etc ,

(2) Assisting the regulatory work regarding Recombinant Drugs, Vaccine, Sera etc as per D & C Rule &Act .

(3) Assisting the Inspection of various regulatory agency like WHO, ANVISA etc to the site of Indian firm .

(4) DGFT related work (Export of Biological Sample.)

(5) Assisting the reply of Parliament Questions

Annexure- VI

Name Swati Srivastava
Drugs Inspector (NZ)

Work allotted at CDSCO (HQ)

1. Work related to Good Laboratory Practices (GLP)
2. Work related to ethics of experiments on animals;
3. Work related to National List on Essential Medicines;
4. Giving input for parliament Question on above topics;
5. Screening of pharmaceutical, chemical, animal and clinical data as per schedule Y of Drugs and Cosmetics Act & Rules for New Drugs Approvals;
6. Screening of applications for Clinical Trial
7. Any other technical work as given by senior officers;

Annexure-VII

Name : Jayant B. Gangakhedkar

Sr. Technical Asstt.(Drugs Control Section)

Duties and Job responsibilities:-

1. Files pertaining to Test Licences in Form 11 and 11A for importing bulk drugs, formulations and biological products;
2. Files pertaining to Adverse Events following Immunization;
3. Files pertaining to Drugs Consultative meeting for the year 2004-05;
4. Files pertaining to DGFT comments for import of drugs (Bulk Drugs);
5. Files pertaining NOC for import of drugs for the distribution to poor and needy patients by the charitable organizations;
6. To maintain files and all data regarding import statistics. To prepare answers to parliamentary questions, to provide data pertaining to import statistics and analytical report Miscellaneous correspondence of Port office and NCB, Gwalior as required from time to time;
7. All files pertaining to large Volume Parenterals (recently shared with another STA);

Annexure-VIII

Dr. Ravi Kant Sharma
Sr . Technical Asstt. (Drugs Control Section)

Details of the work assigned:-

1. Examination of the Applications for the manufacturing of Blood Products in the country;
2. Examination of the applications for the manufacturing of Diagnostic Kits in the country;
3. Registration of the manufacturing site and Blood Products;
4. Registration of manufacturing and Diagnostic Kits;
5. Issue of Form 10 licence and Test Licence for Diagnostic Kits/ Blood Products;
6. Import of Rawmaterials for the manufacturing of Various kits;
7. Export of Diagnostic Kits;
8. Issue of Rule 37 permission for repacking/relabelling in the country;
9. Import of HbsAg Positive Plasma and HIV Positive Plasma for manufacturing of the controls of various kits;
10. DGFT reference regarding the export of Blood Products/ Serum/Plasma;
11. GMP guidelines for Diagnostic Kits;
12. Evaluation of Diagnostic Kits/Blood Products at NIB, Noida and NICD, Delhi;
13. Import of Research Products which are not used for Diagnostic use;
14. Circulation of the kits approved for Blood Bank use;
15. Correspondence with zonal Offices/Port Offices/State Drugs Controller regarding manufacturing and import of Diagnostic Kits and Blood Products;
16. Action taken for the kits which are found of sub-standard quality;
17. Co-ordination with NIB, Noida regarding the testing/evaluation of blood Products;
18. Correspondence with All Indian diagnostic Manufacturer association regarding the various policy matters;
19. Correspondence with NACO regarding the procurement of the kits;
20. Parliament Questions related to Diagnostic Kits and Blood products;

Name: Somnath Basu
Sr. Technical Asstt. (Drugs Control Section)

Details of Job responsibilities:-

1. Examination of clinical trial protocol, Bioequivalence study protocol of New Drugs under Drugs and Cosmetics Act, 1940.

2. Review of published literatures on New Drugs;

3. Examination of protocols to import drugs for R & D works (Test licences)

4. Examination of chemical, pharmaceutical, toxicological, clinical study reports of New Drugs and other under Drugs and Cosmetics Act, 1940.