2. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF BIOLOGICALS AND VACCINES (NEW CHEMICAL ENTITIES/MONITORED RELEASE AND INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Biologics and Vaccines which meets the standards for Quality, Safety and Efficacy of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Vaccines, Biologicals, stem cell, and blood and blood products
Fees to be Paid	:	**New Chemical Entities/Monitored Release** Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF **Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF **Variation-turned-Initial:** Php 15,000.00 + 1% LRF **If additional PV activity(ies) are necessary based on FDA Circular No. 2021-020*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS	
AO No .47-a, series of 2001 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
1 . Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 2. Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
3. Certifications For contract manufacturing:	
a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
4. Site Master File 5. Labeling 6. Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) 7. Product Information a. Package Insert b. Summary of Product Characteristics (Product Data Sheet) 8. Risk Management Plan (RMP) which shall include the following: a. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems b. RMP Philippine-Specific Annex (as applicable) c. RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report 10. List of Countries where the product is already licensed and the date of approval (for vaccines) 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Departmen t, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary	Applicant Company/ Manufacturer (For whole Part II: Quality)

Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development	

P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control • Information on the number system of the lots or batches • System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses • Summary Lot Protocol (for vaccines, toxoids and immunoglobulins) • Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Head to Head Comparability – for biosmilars	
Part III: Nonclinical Document Sec. A Table of Contents	Applicant Company/Manufacturer

Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary 2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology 2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development	(For whole Part III: Nonclinical Document)

2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity	

4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other	
Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations 3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data	

Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References	
Additional Requirements: 1. For products to be registered using Collaborative Registration Procedure (CRP), Expression of Interest submitted to WHO 2. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP. 3. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional	Applicant Company/Manufacturer Applicant Company/Manufacturer

activity(ies) are necessary based on FDA Circular No. 2021-020]	
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL APPLICATION FOR SIMILAR BIOTHERAPEUTIC PRODUCTS	
Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information 1. Integrated Application Form (with proof of payment) 2. Letter of Authorization (where applicable) 3. Certifications For contract manufacturing: a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer For manufacturing "under-license" a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of "under-license" agreement For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific) For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance 4. Site Master File	Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer (For the whole Section C) FDA Website & Cashier

5. Labeling 6. Representative Sample with corresponding Certificate of Analysis 7. Product Information c. Package Insert d. Summary of Product Characteristics (Product Data Sheet) 8. Risk Management Plan (RMP) 9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report 10. List of Countries where the product is already licensed and the date of approval 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	
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S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control • Information on the number system of the lots or batches • System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures	

P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses • Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Quality Comparability P 9.1. Reference Biotherapeutic Product P 9.2. Manufacturing Process P 9.3. Characterization P 9.3.1. Physicochemical Properties P 9.3.2. Biological Activity P 9.3.3. Immunochemical Properties P 9.3.4. Impurities P 9.4. Specifications P 9.5. Analytical Techniques P 9.6. Stability	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Consideration 2. Special Consideration 2.1. In Vitro Studies 2.2. In Vivo Studies	Applicant Company/Manufacturer (For Whole Part III: Nonclinical Document)
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Pharmacokinetic Studies 2. Pharmacodynamic Studies	Applicant Company/Manufacturer (For Whole Part IV:

3. Confirmatory Pharmacokinetic/ Pharmacodynamic Studies 4. Efficacy Studies 5. Safety Studies 6. Immunogenicity 7. Extrapolation of Efficacy and Safety Data Additional Requirements: 1. For products to be registered using Collaborative Registration Procedure (CRP), Expression of Interest submitted to WHO	Clinical Document)
2. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP	Applicant Company
3. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA Circular No. 2021-020]	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*

	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	3. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	Day 1 1 working day	FDA Cashier/Landbank FDAC *Personnel*
	4. Receives the application from FDAC and encodes/updates the database	None		Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing

	5. Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	Day 2-21 20 working days	CDRR-CRR Unit *Personnel*
	6. Decks/Assigns the application to the assigned evaluator of Registration Section and/or Clinical Research Section.	None	Day 22 1 working day	CDRR *Director*
	7. Evaluates the application according to requirements and prescribed standards The registration evaluator determines if the application should be reviewed as a standalone biotherapeutic product or biosimilar then refers the RMP and PMS Protocol (for MR only), safety and efficacy to CRS for evaluation	None	Day 23-72 50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator) / Medical Specialist II*

If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	a. Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS).	None		*FDRO I/II/III/ Medical Specialist II*

	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	Day 73-112 40 working days	*FDRO III*
	9. Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	Day 113 1 working day	*FDRO II*
	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor.	None	Day 114 1 working day	*FDRO III*

	11. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	Day 115 1 working day	*FDRO IV (Supervisor)*
	12. Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	Day 116 1 working day (per batch of applications)	*LRD Chief*
	13. Signs and approves the final decision	None	Day 117 1 working day	*CDRR Director*
	14. Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the CDRR-Records Section	None	Day 118 1 working day	*CDRR-CRR Unit Personnel*
	15. Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output	None	Day 119 1 working day (per batch of applications)	*CDRR-Records Personnel*
3. Receives the CPR/LOD/letter	16. Releases the CPR/LOD/letter to the client.	None	Day 120 1 working day	*AFS - Releasing Section Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, Republic Act No. 7394 Article 31, and Republic Act No. 11215 Article VI Section 23).			**120 working days**	