

한국의약품의 중국진출방안

2011년 8월 25일

C&R Research China 대표 박천일

발표내용

- 한눈에 보는 중국의 의약품 시장
- 직접투자 진출방안
- 신약의 진출방안
- 제네릭 진출방안
- C&R China 활용방안

한눈에 보는 중국의약품시장

- 세계 3위
- 6500개의 GMP 제약공장
- 1만개 GSP의약품 유통회사
- 2만개 종합병원
- 30만개의 약국
- 400만명의 의사

China Pharmaceutical Market

- Presence of Traditional Chinese Medicine
- China is not just one country
- Regional Protectionism
- Complexity: Pricing, Reimbursement, Tender Bidding, even Salary
- Unstable Sales Force
- Weak Marketing Capability
- Generic Competition
- Counterfeit
- CSF(Contracted Sales Force)

China Rx Pharmaceutical market

1. 80% of total market
2. Hospital Oriented, no GP
3. Hospital income mostly depends on Selling Drugs
4. Prevailing Kickbacks to Drs
5. Role of Hospital Director, Pharmacy Director, Vice Hospital Director for Pharmacy

중국진출회사 동향

적극적진출

- 한미
- 동아
- 녹십자
- 신풍
- 일양
- SK
- 대웅
- LGLS

품목진출+ 대표처

- 보령
- 한림
- 영진
- 대원
- 안국
- 현대

중국 적극 진출

- 진출의 당위성
- 중국내 M&A 추세
- 어떤 기업을 인수할 것인가?
 - 이익구조, 위치,유통회사, 원료회사
- 어떤 방법으로 인수할 것인가?
 - 합자회사, 합작회사
 - 투자자금
- 어떻게 운영할 것인가?
 - 제품

신약의 중국진출

- Earlier Licensing to Enjoy Long Peak Sales (Leading Time for Registration, Reimbursement)
- Abundant Money
- Lack of Global Licensing Experience
- Importance of Face to Face Meeting
- Dossier
- License Fee(Upfront+ Milestone), Import Price, Loyalty
- Reference Price
- Trade Mark
- Marketing Involvement

Generic 진출방안

- 어떤 제품을 수출할 것인가?
- 의약품 유통회사 혹은 제약회사
- 수출가
- Deposit Refundable
- Dossier License Fee
- Dossier Preparation at Earlier Stage
- IDL Holder
- Trademark

C&R Research China 활용 방안

- Market Feasibility Study
 - Market Size, Trend
 - Competition
 - Patent
 - Reimbursement
- Global Standard CRO Service
- Partnering



Thanks for your attention!

How to register your valuable product in China?

RA manager Jane, Zhong
C&R Research China

Kinds of Registration

- Imported Chemical Drug/API
 - Generic or NCE
- Local Chemical Drug/API
- Imported Bio Product/API
 - New Bio or Biosimilar
- Local Bio Drug/API

Contents

1. Government Organization and Regulations
2. Product Categories for Chemical Drug
3. Procedure of Registering Imported Drug
4. Application Dossier
5. Clinical Trials for Registration
6. Registration as OTC
7. Important Regulations
8. Product Categories for Bio Drug
9. Expenses for Registration
10. Information Search
11. Frequent Questions from Korean Companies

1. Government Organization and Regulations

- SFDA
 - State Food and Drug Administration
- CDE
 - Center of Drug Evaluation
- NICPBP
 - National Institute for the Control of Pharmaceutical and Biological Products
 - National Institute for Food and Drug Control

1. Government Organization and Regulations

- 《处方药与非处方药分类管理办法》（试行）(Jun, 1999)
- 《药品包装用材料、容器管理办法》（暂行）(Mar, 2000)
- 《中华人民共和国药品管理法》（Feb, 2001）

Drug Administration Law of the People's Republic of China

- 《中华人民共和国药品管理法实施条例》(Aug, 2002)

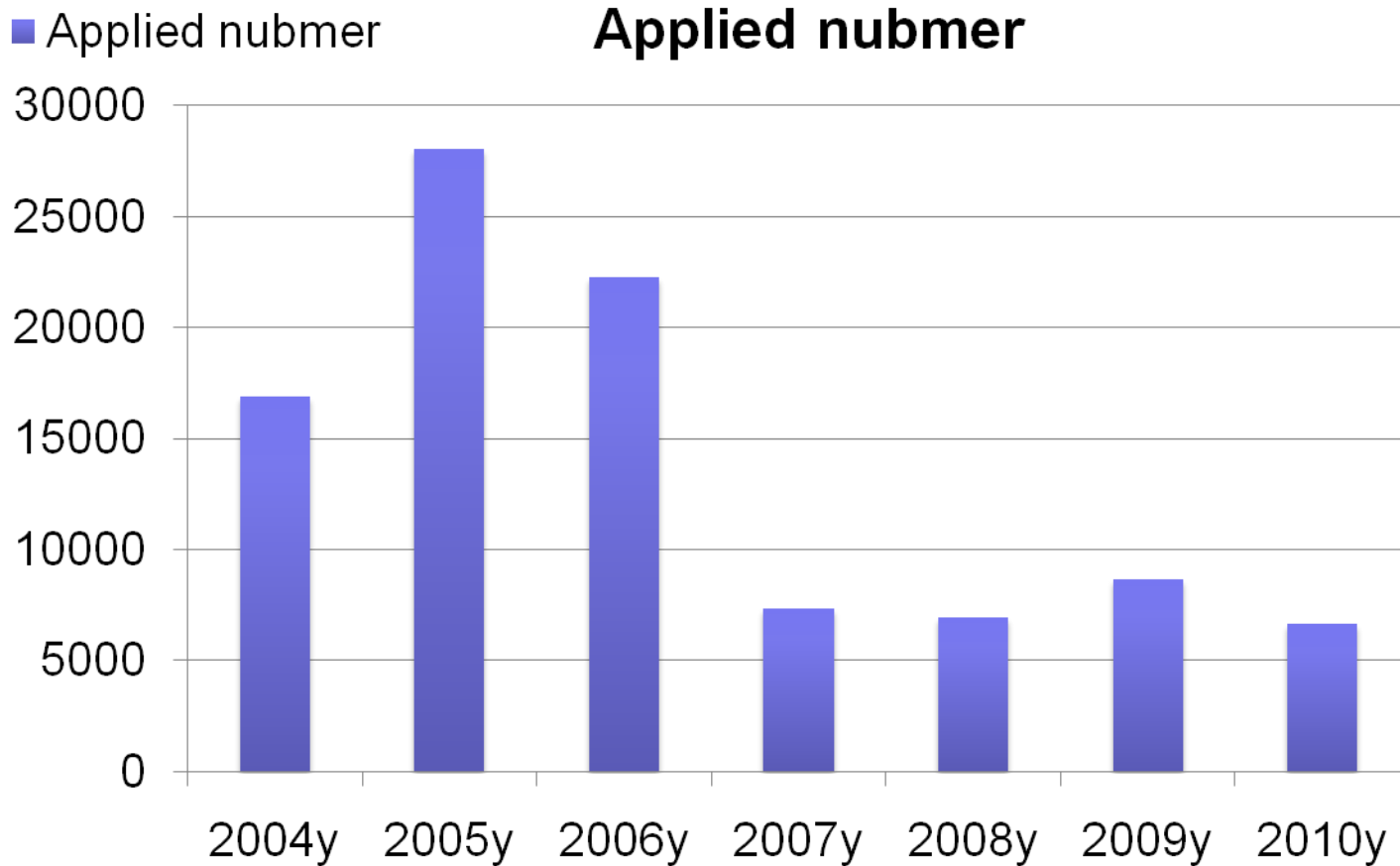
Regulations for Implementation of the Drug Administration Law of the People's Republic of China

- 《药物临床试验质量管理规范》(Jun, 2003)
- 《药物非临床研究质量管理规范》(Jun, 2003)
- 《药品进口管理办法》(Aug, 2003)
- 《生物制品批签发管理办法》(Jun, 2004)

1. Government Organization and Regulations

- 《直接接触药品的包装材料和容器管理办法》 (Jun, 2004)
- 《进口药材管理办法（试行）》 (Oct, 2005)
- 《药品说明书和标签管理规定》 (Mar, 2006)
- 《蛋白同化制剂、肽类激素进出口管理办法（暂行）》 (Sep, 2006)
- **《药品注册管理办法》 (Order 28) Drug Registration Regulation**
- 《药品召回管理办法》 (Dec, 2007)
- 《药品类易制毒化学品管理办法》 (Feb, 2010)
- 《药品生产质量管理规范（2010年修订）》 (Feb, 2011)
- 《药品不良反应报告和监测管理办法》 (May, 2011)

Order 28: Drug Registration Regulation- Background



Drug Registration Regulation

- SFDA Order 28
- Announced on July 18,2007.
- The most important registration regulation.
- Accidents in 2005~2006.

Chapter		Contents
Chapter 1		General Principles
Chapter 2		Basic Requirements
Chapter 3		Clinical Trials of Drugs
Chapter 4		Application and Approval of New Drugs
	Section1	Clinical Trials for New Drugs
	Section2	Production of New Drug
	Section3	Monitoring Period of New Drugs
Chapter5		Application and Approval of Generic Drugs
Chapter6		Application and Approval for Imported drugs
	Section1	Registration of Imported drugs
	Section 2	Approval of Repackaging of Imported drugs
Chapter7		Application of OTC Drugs
Chapter 8		supplementary Application and Approval
Chapter 9		Re-registration of Drugs
Chapter10		Inspection During Drug Registration
Chapter11		Drug Registration Standards and Insert Sheets
	Section1	Drug Registration Standards
	Section2	Drug Standard Substance
	Section3	Drug Name, Insert Sheets and Labels
Chapter12		Prescribed Timeline
Chapter13		Reconsideration
Chapter14		Legal Liability
Chapter15		Miscellaneous

Drug Registration Regulation

Annex	Contents
Annex 1	Registration Categories and Application Information Requirements of TCM and Natural Drugs
Annex 2	Registration Categories and Application Information Requirements of Chemical Drugs
Annex 3	Registration Categories and Application Information Items Requirements of Biological Products
Annex 4	Registration Items and Application Information Requirements supplementary Application of Drug Registration
Annex 5	Application Information Items of Drug Re-Registration
Annex 6	Timeframe for monitoring period of New Drugs



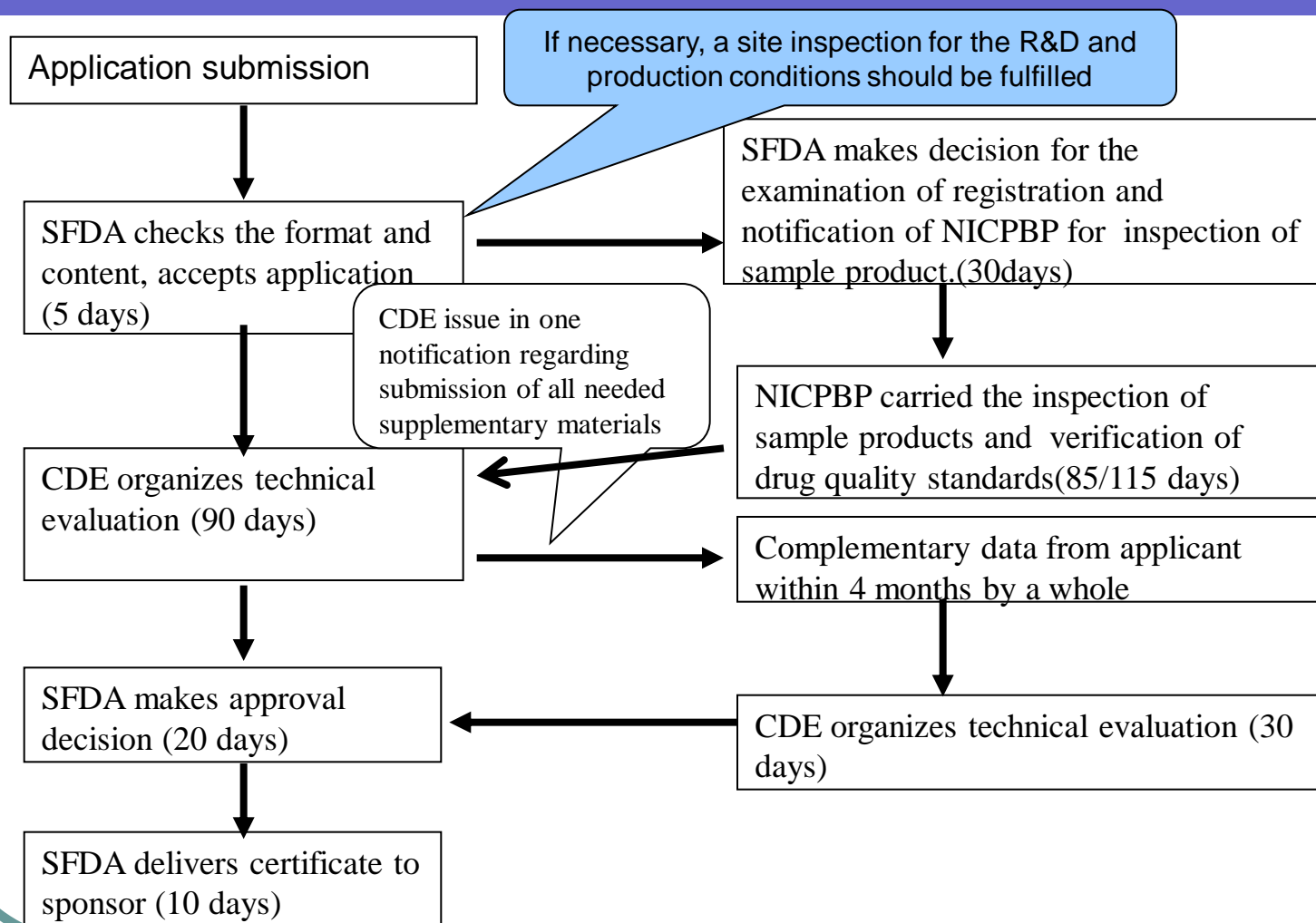
2. Product Categories for Chemical Drug

Category	Description	
Category 1	New chemical entity never marketed in any country.	
	1.1	Drug substance and its preparations made by synthesis or semi-synthesis
	1.2	Chemical monomer(including drug substance and preparation) extracted from natural sources or by fermentation.
	1.3	Optical isomer(including drug substance and preparation)obtained by chiral separation or synthesis
	1.4	Drug with fewer components derived from marketed multi-component drug
	1.5	New combination products
	1.6	A preparation already marketed in China but with a newly added indication not yet approved in any country
Category 2	Drug preparation with changed administration route and not marketed in any country	
Category 3	Drug marketed ex-China, including	
	3.1	Drug substance and its preparations, and/or with changed dose form, but no change of administration route
	3.2	Combination preparations, and/or with changed dose form, but no change of administration route
	3.3	Preparations with changed administration route and marketed ex-China
	3.4	A preparation already marketed in China but with a newly added indication approved ex-China
Category 4	Drug substance and its preparation with changed acid or alkaline radicals(or metallic elements), but without any pharmacological change, and the original drug entity already approved in China	
Category 5	Drug preparation with changed dose form, but no change of administration route, and the original preparation already approved in China	
Category 6	Drug substance or preparation following national standard.	



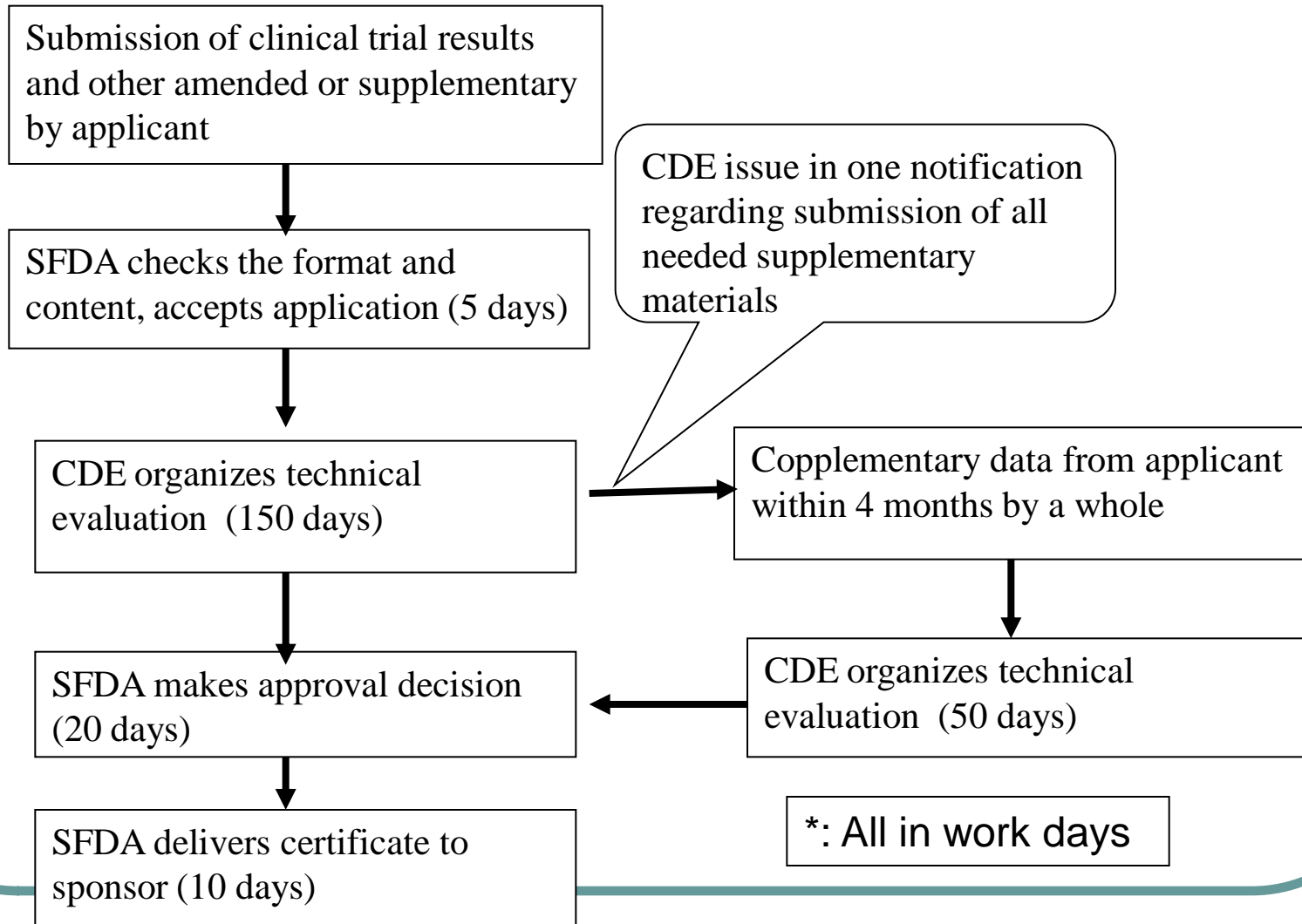
3. Procedure of Registering Imported

3. Process of Registering Imported Drug --Clinical Trial Application

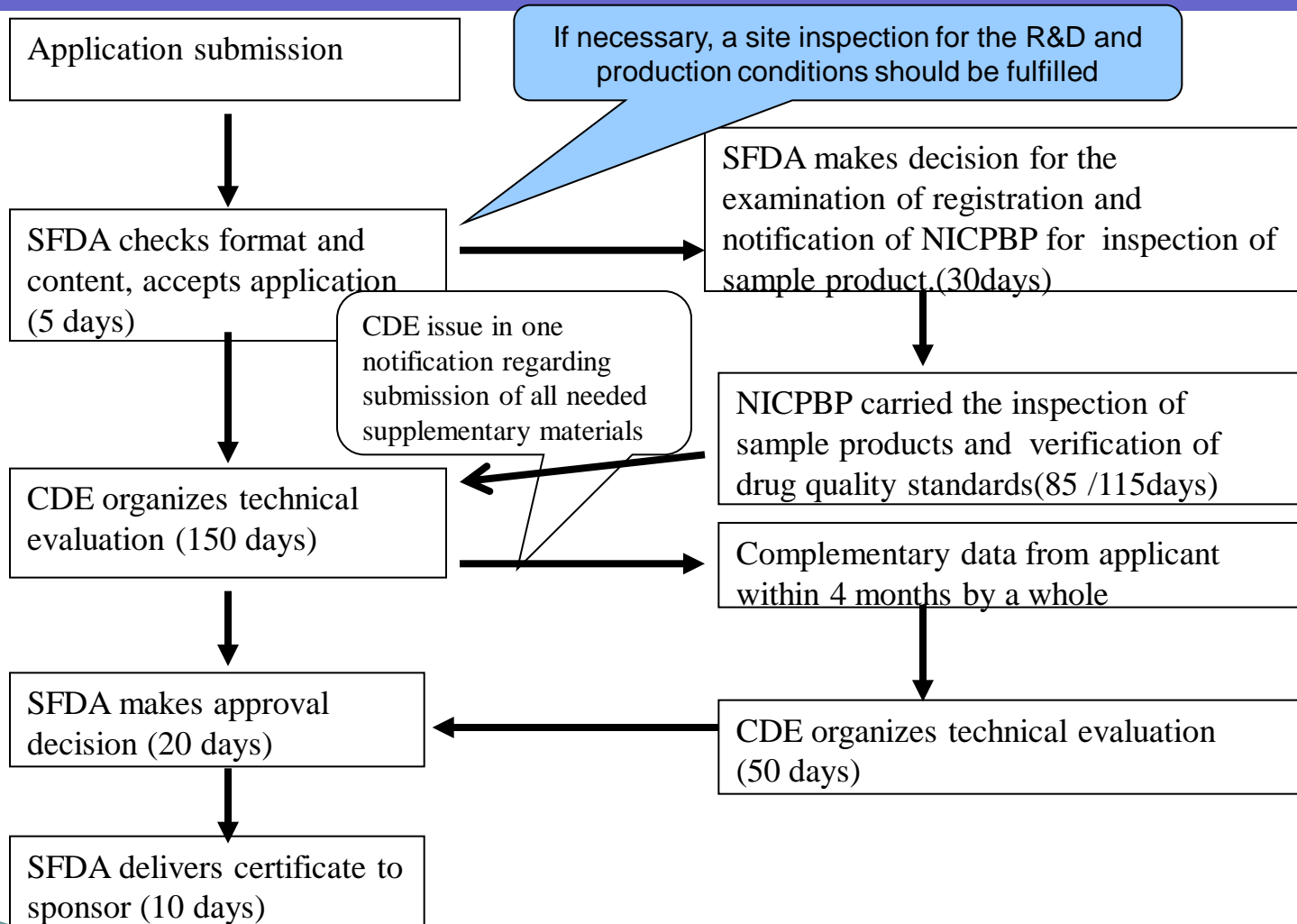


*:Sample inspection and drug quality standard verification for special drugs and vaccine products should be completed within 115 days.

3. Process of Registering Imported Drug ---IDL Application (After Clinical Trial finished)



3. Process of Registering Imported Drug – Clinical Trial exemption



*:Sample inspection and drug quality standard verification for special drugs and vaccine products should be completed within 115 days.

Registration Timeline

Application	Ideal Timeline	Supplementary needed	Actual Timeline (Most)	Remark
Clinical Trial Exemption(IDL)	11 months	15~18 months	≥ 15 months	Not including dossier preparation period
CTA	8 months	11~14 months	≥ 11 months	
IDL	11 months	15~18 months	≥ 15 months	



- **4. Application dossier**
---Chemical drug

4. Application dossier for CTA

Part A Summary	Part B Pharmaceutical Study Information	Part C Pharmacology and toxicology study information	Part D Clinical Study Information
<p>Item 1 Name of the drugs.</p> <p>Item 2 Certified Documents.</p> <p>Item 3 Objectives and basis for R & D.</p> <p>Item 4 Summary of main study work.</p> <p>Item 5 Draft of packaging insert, note to the draft, and latest literature.</p> <p>Item 6 Design of packaging and labeling</p>	<p>Item 7 Summary of Pharmaceutical Study,</p> <p>Item 8 Research information and relevant literature of formula and process of the preparations. Research information and relevant literature of the production process of the drug substance.</p> <p>Item 9 Study information and relevant literature for the chemical structure and components determination.</p> <p>Item 10 Study information and literature for quality specification</p> <p>Item 11 Draft of quality specification and notes, and providing reference standard.</p> <p>Item 12 Test report of drug sample.</p> <p>Item 13 The source, test report and quality specification of drug substance and excipient.</p> <p>Item 14 Stability study and relevant literature.</p> <p>Item 15 Selection basis and quality specification of immediate packing material and container.</p>	<p>Item 16 Summary of pharmacology and toxicology study.</p> <p>Item 17 Primary pharmacodynamics study and literature.</p> <p>Item 18 General Pharmacology study and literature.</p> <p>Item 19 Acute/single dose toxicity study and literature.</p> <p>Item 20 Repeated dose toxicity study and literature.</p> <p>Item 21 Special safety study and literature of hypersensitive (topical, systemic and photo-toxicity), hemolytic and topical irritative (blood vessel, skin, mucous membrane, and muscle) reaction related to topical and systemic use of the drugs.</p> <p>Item 22 Study and relevant literature on Pharmacodynamics, toxicity and pharmacokinetics change caused by the interactions amongst multiple components in the combination products.</p> <p>Item 23 Study and literature of mutagenicity test.</p> <p>Item 24 Study and literature of reproductive toxicity.</p> <p>Item 25 Study and literature of carcinogenicity test.</p> <p>Item 26 Study and literature of drug dependence.</p> <p>Item 27 Study and literature of pre-clinical pharmacokinetics</p>	<p>Item 28 Summary of global clinical study information.</p> <p>Item 29 Clinical study protocol.</p> <p>Item 30 Investigator's Brochure.</p>

4. Application dossier for IDL(imported drug licence)

After Clinical Trial submission:

- Item1 Name of the drugs.
- Item2 Certified Documents.
- Item3 Objectives and basis for R & D.
- Item4 Summary of main study work.
- Item5 Draft of packaging insert, note to the draft, and latest literature.
- Item6 Design of packaging and labeling.
- Item12 Test report of drug sample.
- Item14 Stability study and relevant literature.
- Item28 Summary of global clinical study information.
- Item29 Clinical study protocol.
- Item30 Investigator's Brochure.
- Item31 Draft of Informed Consent Form, approval of the Ethics Committee.
- Item32 Clinical study report.

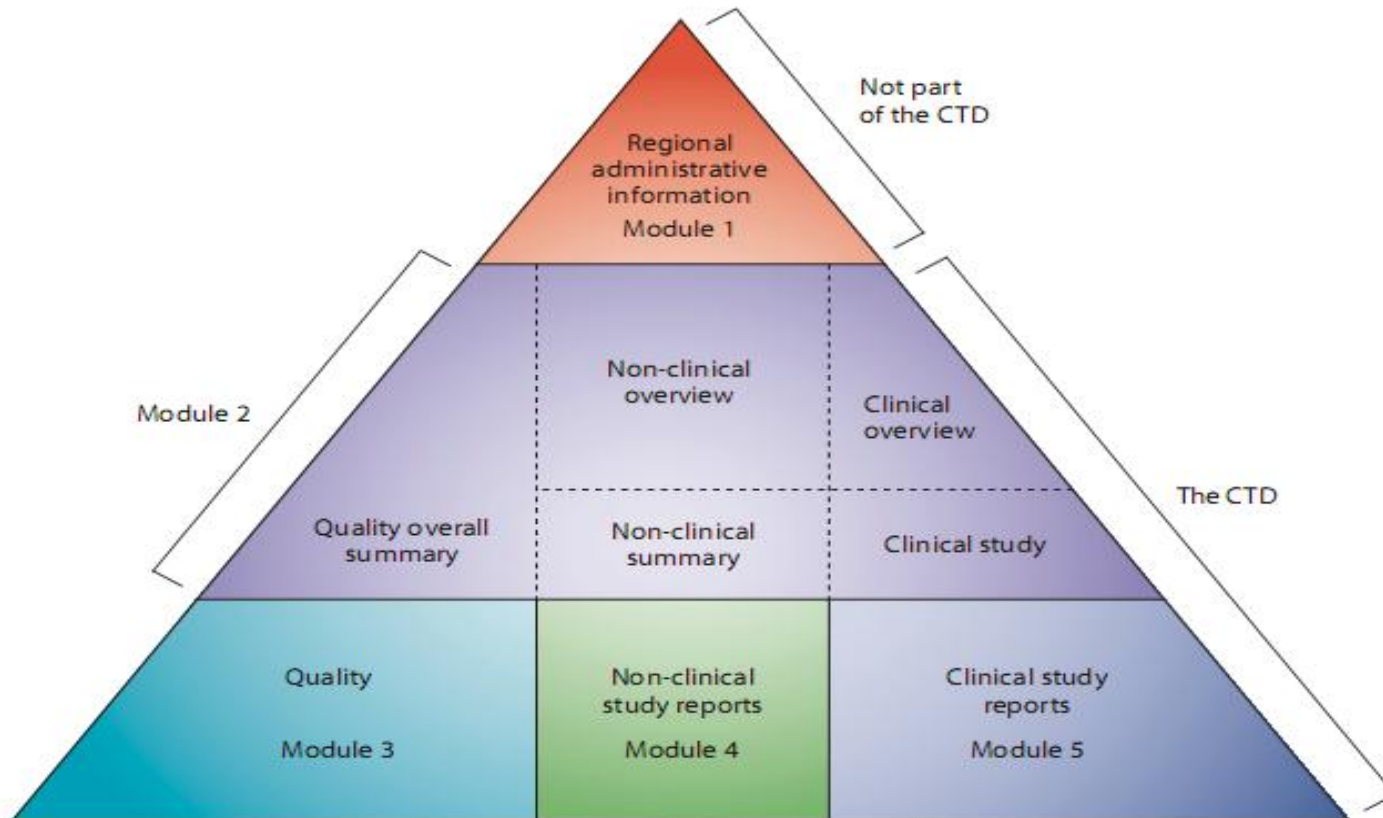
● **Other information/data recently changed or supplementary data.**

4. CTD format application dossier -the latest requirements from SFDA

- CTD: Common Technical Document
- Reference to ICH M4
- 《关于按CTD格式撰写化学药品注册申报资料有关事项的通知》 - 国食药监注[2010]387号(Chemical drug)

Category	Part	CTD format	
Category 3, 4, 5, 6	A Summary	CTA	No
		IDL	No
	B Pharmaceutical Study Information	CTA	No
		IDL	Yes
	C Pharmacology and toxicology study information	CTA	No
		IDL	No
	D Clinical Study Information	CTA	No
		IDL	No
Category 1,2	A Summary	CTA	No
		IDL	No
	B Pharmaceutical Study Information	CTA	No
		IDL	No
	C Pharmacology and toxicology study information	CTA	No
		IDL	No
	D Clinical Study Information	CTA	No
		IDL	No

CTD Triangle



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

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The CTD triangle. Click to view PDF.

M4 : The Common Technical Document

The agreement to assemble all the Quality, Safety and Efficacy information in a common format (called CTD - Common Technical Document) has revolutionised the regulatory review processes, led to harmonised electronic submission that, in turn, enabled implementation of good review practices. For industries, it has eliminated the need to reformat the information for submission to the different ICH regulatory authorities.

The CTD is organised into five modules. Module 1 is region specific and Modules 2, 3, 4 and 5 are intended to be common for all regions. In July 2003, the CTD became the mandatory format for new drug applications in the EU and Japan, and the strongly recommended format of choice for NDAs submitted to the FDA.

More information: An [electronic version of the Common Technical Document \(eCTD\)](#) can be produced using the information developed by the eCTD Implementation Working Group.

[M4\(R3\): Organisation](#)[M4Q\(R1\): Quality](#)[M4S\(R2\): Safety](#)[M4E\(R1\): Efficacy](#)

4. Application dossier -Notes

- **Information Item 2, Certified Documents**
 - CoPP (WHO format and notarization required)
 - GMP (WHO format and notarization required)
 - Authorization Letter (notarization required)
 - Business License
 - Patent Statement (Guarantee letter)
- Valid Period (Preparing at late state of dossier assembling period).

4. Application dossier -Notes

Information Item 8, Research information of the production process of drug substance

- **Description of Manufacturing Process and Process Controls**

- Flow diagram
- Starting materials
- Quantities of raw materials, solvents, catalysts, reagents.
- Identification of critical steps
- Reaction conditions(temperature, pressure, duration, catalyst)
- Process controls
- Refining method

- **Control of Materials**

- **Controls of Critical Steps and Intermediates**

- **Process Validation and/or Evaluation**

- **Manufacturing Process Development**

- Producing nonclinical, Clinical, Pilot, Scale-up.
- The raw material input, and output yield
- Possible impurities or other by-products

4. Application dossier -Notes

Information Item 8, Research information of formula and manufacturing process.

Pharmaceutical Development

- Formulation design, screen and optimization.
- Manufacturing Process Development.
 - Lab-scale →pivotal clinical batches.
 - Selection and optimization of the manufacturing process.
- Container closure system(suitability).
- Manufacture.
 - Batch Formula.
 - Description of Manufacturing Process and Process Controls.
 - Intermediate tests or final product controls.
- Controls of Critical Steps and Intermediates.
 - Numeric ranges for critical steps should be justified.
- Manufacturing Process validation.

4. Application dossier -Notes

Information Item 10, Study information of quality Specification

- Quality control items: Dissolution, Assay, Impurities, pH, ionic strength, redispersion, particle size distribution, polymorphism, rheological properties, biological activity or potency etc.
- Specification.
- Analytical Procedures.
- Validation of Analytical Procedures.
- Batch Analysis.

4. Application dossier -Notes

Information item 14, experiments information and literature of the stability study of the drugs

- Stress testing (Influence testing: Temperatures, Humidity, Photolysis).
- Accelerated testing ($40 \pm 2^{\circ}\text{C}$, $75\% \pm 5\%\text{RH}$).
- Long-term testing ($25 \pm 2^{\circ}\text{C}$, $60\% \pm 5\%\text{RH}$).
- Container Closure System.

4. Application dossier -Notes

Item 17 Primary pharmacodynamics study and literature.

Item 18 General Pharmacology study and literature.

Item 19 Acute/single dose toxicity study and literature.

Item 20 Repeated dose toxicity study and literature.

Item 23 Study and literature of mutagenicity test.

Item 24 Study and literature of reproductive toxicity.

Item 25 Study and literature of carcinogenicity test.

Item 27 Study and literature of pre-clinical pharmacokinetics

- Can be replaced by literature for Generic Drug(Category 3).
- Can't be replaced by literature for New Drug (Category 1).
- For Item 27(Category 3), Sustained or controlled released preparations(significant increase in dosage, obvious safety concerns).
 - Animal pharmacokinetic study information compared with the marketed sustained released preparations should be provided at single dose.

4. Application dossier -Notes

- **Item 21** Special safety study and literature of hypersensitive (topical, systemic and photo-toxicity), hemolytic and topical irritative (blood vessel, skin, mucous membrane, and muscle) reaction related to topical and systemic use of the drugs.
- For the drugs for topical use.
- Topical absorption test should be conducted, if necessary.

4. Application dossier -Notes

- **Item22** Study and relevant literature on Pharmacodynamics, toxicity and pharmacokinetics change caused by the interactions amongst multiple components in the combination products.
- **Item26** Study and literature of drug dependence.
- Acting on central nervous system(analgesics, depressants, stimulants).



5. Clinical Trials for Registration

5. Clinical Trials for Registration

- Cases of patients for clinical trials should meet be statistical requirement.

Category	The minimal cases required
Category1	20-30 for Phase I , 100 for Phase II , 300 for Phase III,
Category2	20-30 for Phase I , 100 for Phase II , 300 for Phase III
Category3	Pharmacokinetic Study; At least 100 pairs(60 pairs/one indication)
Category4	Pharmacokinetic Study; At least 100 pairs(60 pairs/one indication)
Category5	18~24(Bioequivalence); At least 100 pairs; Controlled Pharmacokinetic Study; At least 100 pairs;(Sustained Release)
Category6	18~24(Bioequivalence) ← oral solid Exemption←item 28 (Y) At least 100 pairs ← item 28(N) At least 100 pairs ← process and standards

5. Clinical Trials for Registration

Exemption of Clinical Trials

- Summary of Clinical study(item 28): ICH CTD M4E-R1
- Comparative study (Quality control):
 - Impurities (Species and Quantity)
 - Safety (Excipients) .

5. Clinical Trials for Registration

- Clinical Trial Sites
 - Selecting from the qualified institutions(394);
- Clinical Trial Drugs: GMP;
- Drugs inspection;
- Filing in SFDA(Copy in PDA): Before conducting the clinical trial;
- Clinical study shall start within 3 years of approval.

5. Clinical Trials for Registration

- International multi-center clinical study:
 - Chemical drug: Already registered in a foreign country or in Phase II or phase III clinical trials.
 - New preventive vaccine: Registered outside China.

6. Registration as OTC

- In June 1999(1 Jan, 2000)
- Application for OTC products
 - 1.Generic name in OTC drug list (5000);
 - 2. Change in dosage form, but without change in indications, dosage, route of administration of an OTC drug;
 - 3. New combination preparations developed from active OTC ingredients.
- Insert and label.

Clinical Trial-OTC

Classification	Clinical Trial	Remarks
1. OTC listed	Oral solid: Bioequivalence Others: No	
2. Change in dosage form		
3. New combination	If necessary	Basis of formulation

6. Registration as OTC

- Not yet listed in SFDA
 - Apply as Rx.
 - >3~5 years' Rx marketing.
 - Apply OTC.



7. Important Regulations

7. Important Regulations

- **Patented Product in China:**
 - 2 years prior to the patent expiration;
- **Post Marketing Surveillance(PMS) period**
 - Local product.
 - ≤ 5 years
 - Effective when start producing within 2 years date.

7. Important Regulations

- **Green Path(Special approval process)**
 - Active ingredients and its preparation extracted from plant, animal and minerals which have not been marketed in China;(Domestic)
 - Chemical drug raw material and its preparations, or biological product that have not been marketed in global;(Domestic)
 - New drugs for AIDS, cancer and orphan disease that are superior to the marketed drugs.
 - New drugs which treat diseases for which there is no effective therapy.

7. Important Regulations

- New Drug under Registration Category 1 should be those that are at least in the stage of Phase II Clinical Trials ex-China.
- **Registration Inspection (NICPBP):**
 - Inspection of sample product.
 - Verification of drug quality standards.
 - 3 batches drug samples .
 - 3 times of the amount of the sample needed in quality standard testing.

7. Important Regulations

- **Immediate packaging materials or containers :**
Documents to evidence the legal channels .
- **Drug raw material and excipients:**
Evidence the legal channels—DMF, CTD.

7. Important Regulations

- **Repackaging of Imported drugs**
- ***Imported Drug Certificate.***
- Not yet manufactured in China or, not able to meet the clinical demand.
- Period not exceeding the valid period of Imported Drug Certificate.
- With exception of tablet or capsule, internal packing of repacked drugs in all other dosage form should be finished offshore.
- Application: at least one year prior to expiration of ***Imported Drug Certificate.***
- Repackaged by one production company.
- supplementary Application.

7. Important Regulations

Supplementary Application

- **Approval by SFDA**

- Changes of items in the approval certificate or its attachment.
- Change of production process.
- Amendment of drug registration quality standard.
- Change of excipients in the formula.
- Change of manufacturing location of raw material used for preparation.

- **Changes study guideline published by CDE.**

7. Important Regulations

supplementary application

- Filing in SFDA
 - Change in drug appearance with no change in drug quality standards.
 - Amendment of insert sheet according to the National standard or requirement of SFDA
 - Supplementing safety information of insert sheet.
 - Change of design of packaging or label as requested by regulation.

7. Important Regulations

Extend IDL (Re-registration)

- Valid period of IDL: 5 years.
- Apply 6 months prior to the expiration.
- Timeline: 6 months.



8. Product Categories for Bio Drug

- A Therapeutic Biological Products
- B Preventive Biological Products

Category	Description
Category 1	<i>Biological products not yet marketed at domestic or overseas</i>
Category 2	Mono-Clonal Antibody
Category 3	Gene therapy, somatic cell therapy as well as the preparations
Category 4	Allergen products
Category 5	Multi component products with bioactivity extracted from, or by fermentation from human and/ or animal tissues and/ or body fluid
Category 6	New combination product made from the already marketed biological products
Category 7	<i>A product that is marketed already overseas but not yet marketed domestic</i>
Category 8	Some of the strains used for preparing of micro-ecological products not yet approved
Category 9	Products with not completely same structure with already marketed products and not yet marketed at domestic or overseas(including Amino Acid Locus Mutation/Absence, modification caused by a different expression system, deletion, changed interpretation, as well as chemical modifications of the product).
Category 10	Products with a method of preparation different with the already marketed one, (such as use of different expression system, host cells).
Category 11	Products first time made with DNA recombination technology (such as use of recombination technology to replace the synthesis technology, tissue extration or fermentation technology).
Category 12	Products transformed from non-injection into injection, or topical use into systemic use, and not yet marketed at domestic or overseas
Category 13	The marketed products with a change in dosege form but no change in route of administration
Category 14	Products with a change in route of administration (excluding the above Category 12)
Category 15	<i>Biological products admitted with National Standards.</i>

Category	Description
Category 1	<i>Vaccine not yet marketed at domestic or overseas</i>
Category 2	DNA vaccine
Category 3	A already marketed vaccine with new adjuvant. Change of carrier of combined vaccine
Category 4	Non-purified vaccine, or full cell vaccine(bacteria, virus) changed into purified vaccine, or combined vaccine
Category 5	Vaccine with strais not yet approved in China(except for vaccine for influenza, vaccine for leptospirosis and others)
Category 6	<i>Vaccine already marketed overseas but not yet marketed domestic</i>
Category 7	Combined vaccine prepared with already marketed domestic
Category 8	Re-combination vaccine with protective antigen spectrum different with the marketed one
Category 9	Vaccine manufactured with the change of the other approved expression or the other approved cellular stroma. Vaccine using new process, which is proved to improve the safety and effectiveness of the vaccine based on the data of laboratory
Category 10	Vaccine with change of de-activator (method of deactivation) or de-toxicitor(method of de-toxicity).
Category 11	Vaccine with change in the route of administration.
Category 12	A domestic marketed vaccine with change in dosage form but no change in route of administration
Category 13	Vaccine with dosage of immunity or immunity procedure
Category 14	Vaccine with an enlarged group of people(enlarged age range)
Category 15	<i>Vaccine admitted with National Standards.</i>



9. Expenses for Registration

Items	Expenses(RMB)	Remark
SFDA review	45,300	
NICPBP Inspection (QC test)	~50,000	1 Strengthen, 3 batches products
Dossier translation	?	
CRO professional service fee	400,000~500,000	
Clinical Trial	?	



10. Information Search

- www.sfda.gov.cn
 - National Drug data
 - Imported Drug data
 - Applied Drug data
 - Clinical Approval Drug data
 - Qualified institutions for Drug Clinical Trial
 - Registration Stage



State Food and Drug Administration, P.R.China

Chinese(GB)

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1. 阿司匹林肠溶片 QH20090978 Bayer S.p.A. 86979288000043)
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- 20110707 药审中心启动CTD申报资料预审工作
- 20110706 药审中心召开生物统计学部审评系统软硬件方案专家论证会
- 20110704 关于按CTD格式申报药理学资料及相关审评工作的补充说明
- 20110607 关于化学原料药和制剂申请关联审评事宜的通告

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- 20110804 关于开展药用非吸入式气雾剂生产企业氯氟化碳(CFCs)消耗量数据核查的通知
- 20110804 国家食品药品监督管理局发布2011年第2期国家药品质量公告
- 20110802 关于获取2011年第十期(上海)研讨班参会通知及相关参会注意事项
- 20110801 国家食品药品监督管理局加强接受境外制药厂商委托加工药品监督管理
- 20110801 国家食品药品监督管理局公布第二十四批允许发布处方药广告的医学药学专业刊物名单
- 20110801 关于明确尼美舒利缓释制剂说明书中用法用量项有关内容的通知

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- 20110323 关于CDE网站增设“审评交流”栏目的通知
- 20110321 药审中心加强与企业的沟通与交流



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- 20110804 非临床安全性和有效性评价 体内微核试验的自动化分析
- 20110803 临床安全性和有效性评价 核苷(酸)类似物治疗慢性乙型肝炎III期临床试验回顾
- 20110727 综合评价 生物利用度及生物等效性研究中试验样品的提供与管理
- 20110701 临床安全性和有效性评价 治疗精神分裂症药物临床试验的一般考虑

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- 20090813 关于新法规品种临床期间修改处方工艺的几点
- 20090813 羟乙基淀粉系列产品研究中需关注的问题(二)--羟乙基淀粉200/0.5原料药及制剂研究需关注的问题
- 20090810 “新法规下化药仿制药研究和评价中的关键问
- 20090810 羟乙基淀粉系列产品研究中需关注的问题(一)--立意方面的问题

研究课题

- “十五”攻关:用于抗感染、抗肿瘤和心血管药物临床试验对照药品的示范研究
- 国家科技支撑计划:中药研发与上市前技术评价标准的研究(2006BAI21B10)

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- 药物致癌试验必要性的技术指导原则 [20100422颁布]
- 化学药物长期毒性试验技术指导原则 [2007-08-13 16:09:39颁布]
- 抗高血压复方药物临床研究指导原则 [2007-08-13 16:13:46起草]
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- 化学药物非临床药代动力学研究技术指导原则 [2007-08-23 13:52:06颁布]
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11. Frequent Questions from Korean Companies

1. Exemption of Clinical Trial;
2. Manufacturing process development;
3. Stability study;
4. Quality control study;
5. Comparative study;
6. Corresponding chromatograph or photograph in study.
7. Compatibility study (**Impurities**).
8. Study information of analysis method of **degradation substance**.

Stability study protocol

- Source , Batch No. of drug substance and excipients
- Batch No, Batch Scale.
- Source of package material or closure system.
- Inspection items.
- Testing methods.
- Accepted limited value
- Inspection time point.
- Storage condition.
- Plan of stability study
- Data analysis and evaluation.
- Stability study results
- Valid period
- Promising of stability study.

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