What’s New in the Drug Regulatory System and KFDA

July 1, 2010

Korea Food and Drug Administration

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- Regulatory Infrastructure
- Review and Approval Process
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KFDA Organization

Commissioner

Deputy Commissioner

Audit and Inspection Officer

Spokesperson

General Services Division
- Planning and Budget Officer
- Administrative Management Officer
- Regulatory Reform and Legal Affairs Officer
- International Trade and Statistics Officer
- Information Management Officer
- Customer Support Officer

Director General for Planning & Coordination
- Risk Prevention Policy Bureau
- Risk Information Division
- Laboratory Audit & Policy Division
- Clinical Trials Management Division

Risk Prevention Policy Bureau
- Food Safety Policy Division
- Food Management Division
- Foodborne Diseases Prevention and Surveillance Division
- Foreign Inspection Division
- Food Import Division
- Narcotics Control Division

Food Safety Bureau
- Pharmaceutical Safety Bureau
- Pharmaceutical Policy Division
- Pharmaceutical Management Division
- Pharmacetical Quality Division
- Cosmetics Policy Division

Pharmaceutical and Herbal Medicine Bureau
- Biopharmaceuticals
- Medical Device Safety Bureau
- Biopharmaceutical Policy Division
- Medical Device Policy Division
- Medical Device Management Division
- Medical Device Quality Division

Medical Device Evaluation Bureau
- Medical Device Evaluation Department
- Diagnostic Medical Devices Division
- Therapeutic Medical Devices Division
- Medical Materials and Supplies Division

National Institute of Food and Drug Safety Evaluation

6 Regional KFDA Offices
- Drug Evaluation Department
- Biologics Division
- Advanced Therapy Products Division
- Herbal Medicinal Products Division
- Cosmetics Evaluation Division

- Food Standardization Department
- Dietary Life Safety Division
- Medical Device
- Novel Food Division

- Food Standardization Division
- Health/Functional Food Standardization Division
- Food Additives Standardization Division

- Drug Approval and Review Management Division
- Pharmaceutical Standardization Division
- Cardiovascular and Neuropharmacological Drugs Division
- Oncology and Antibiotics Division
- Gastroenterology and Metabolism Products Division
- Bioequivalence Evaluation Division
126 government officials
90 contract workers
(As of June, 2010)
Pharmaceutical Safety Bureau

Activities

✓ Marketing Authorization
✓ Clinical Trial Review
✓ Advertisement Regulation
✓ Post-Marketing Surveillance
✓ Quality Control
Regulatory Infrastructure

- Regulatory hierarchy on Clinical Trials & Drug Approval
  - Pharmaceutical Affairs Law
  - Enforcement Rule of Pharmaceutical Affairs Law
  - Guideline
    - Guideline on GCP
    - Guideline on IND
    - Guideline for Accredited Clinical Institutes
    - Regulation for Review and Approval of Drugs
    - Regulation for Review and Approval for Biological Products

- Continuous legalization efforts to support Regulatory Harmonization in order to achieve globalization
Objective
To assure the safety, efficacy and quality of drug products consumed in the domestic market

Subject

- **Approval**
  - Headquarters
    - Items require safety efficacy review and management

- **Notification**
  - Local agency
    - Items do not require safety and efficacy review
**Review and Approval Process of IND & NDA**

- **Pre-IND Meeting**
- **IND Application KFDA Review (30 days)**
- **NDA Submission**
- **NDA Approval**
- **Phase IV**

1. **Pre-clinical Development**
2. **Phase I Clinical Trial**
3. **Phase II Clinical Trial**
4. **Phase III Clinical Trial**
5. **NDA Approval**

**CPAC**
- Consultation
- KFDA Review (120 days) (including pre-review for 5 days)

*CPAC: Central Pharmaceutical Affairs Advisory Committee*

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**Sponsors have submitted application as electronic documents through KiFDA online system since Oct. 2nd, 2006**
Drug Approval Process

Application

- Research and development of drug
- Prepare dossier for drug approval
  (Article 31, 42 of Pharmaceutical Affairs Law)

Preliminary Evaluation

- Drug Approval & Review Management Division, KFDA
- Write a preliminary report
  - Application Outline
  - Examine the application
- Preliminary review results
  - Review of technology by an area
    - safety, efficacy data
    - quality
    - bioequivalence and compare clinical trials
    - GMP / DMF data, etc
  - Review of social impacts

Evaluation

- Drug Evaluation Department, KFDA

Issuing the certificate of approval

Confirmation of approval

- Applicant

Applicant
Data Requirements of NDA

CMC GMP

Non Clinical Pharmacology ADME Toxicology

Clinical Phase I Phase II Phase III

Bridging

DMF

CPP, etc

Safety and Efficacy Evaluation
Dossier for Safety & Efficacy Evaluation

Origin or backgrounds leading up to discovery and development

- Structure: physical, chemical and biological nature
  - A. Drug Substance
  - B. Drug Product

Stability test data
- A. Drug Substance
- B. Drug Product
  - Long-term, accelerated, stressed

Toxicity
- A. Single dose toxicity
- B. Repeated dose toxicity
- C. Genetic toxicity
- D. Carcinogenicity
- E. Reproductive and developmental toxicity
- F. Others: antigenicity, immunotoxicity, local toxicity dependency, etc.

Pharmacologic effects
- A. Efficacy studies data
- B. Safety or general pharmacology studies data
- C. ADME
- D. Other pharmacologic effects

Clinical data
- A. Clinical data package
- B. Bridging Data

Comparison with domestic copies & special features of the drug concerned

Uses in other countries

Clinical data package

Bridging Data
Bridging Concept

**New Product**

“Bridging Data” = “Korean Data”
“Bridging Study” = “A trial conducted for the Korean People”

**Ethnic Factors**
(Ethnic differences)

- Intrinsic factor (genetic)
- Extrinsic factor (culture, the environment)

**Approval in Korea**

**Evaluation**

- Ethnic Sensitivity
- Foreign Clinical Data
- Bridging Data
KDMF Introduction

- KDMF: API registration system
  *(effective as of July 1st, 2002)*

**Background**

- Concerns about using low quality of drug substances
- Quality control of drug substances

**Scope**

- New chemical entities used as APIs
- Phase-in of other APIs registration (designated by KFDA)

*Only drug substances registered can be used.*
Revision of KGMP Regulation

Background
- To improve the current KGMP to the international level
- Korean pharmaceutical companies could be internationally competitive
- International collaboration on GMP like PIC/S

Major Changes
- Pre-approval KGMP (Product-based)
- Process Validation
KFDA Good Review Practices

- Objective
  - Guarantee of quality, efficiency, clarity, transparency, consistency of review results
- After Feb 4, 2004, KFDA has engaged in GRP
- Review template for Pharm/Tox and clinical data review
- Training programs for reviewer
- Disclosure of review results after approval
- Dialogues between customers and the KFDA
Data Exclusivity (PMS)

PMS is to examines/identifies any adverse events not occurred in the course of development and to reflect such results in the approval items.

Additional Terms and Conditions for Product Registration
- Data Exclusivity

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<thead>
<tr>
<th>Period</th>
<th>Classification of Drug</th>
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<tbody>
<tr>
<td>6 Years</td>
<td>- New Drugs</td>
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<tr>
<td></td>
<td>- ETC drugs of which active ingredient or mixture ratio is different</td>
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<tr>
<td></td>
<td>- ETC drugs of which active ingredients are identical with different administration routes</td>
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<tr>
<td>4 Years</td>
<td>- ETC drugs of which active ingredients and administration routes are identical with explicitly different efficacy and efficiency added.</td>
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<td>- Other drugs requiring re-examination</td>
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Plan in KFDA

- Participate in International Harmonization Meetings such as ICH, APEC, China-Japan-Korea meeting
- Harmonize with International Standard
- Adopt CTD, GRP to reduce time-waste and improve transparency
- Electronic Civil Petition Window Service
  - Submission, status progress, result can be seen on PC screen
  - Online Certificate Service
  - Video Processing of Civil Petitions
Ohsong Life Science Park

Moving in: Nov, 2010

CyberMap

Seoul

Ohsong

Ochang Scientific Industrial Complex

Daejeon

Daedeok Research Park
Korea Food and Drug Administration (KFDA)
National Institute of Food and Drug Safety Evaluation (NIFDSE)
Center for Disease Control (CDC), National Institute of Health (NIH)
The Korea Health Industry Development Institute (KHIDI)
Korea Human Resources Development Institute for Health and Welfare (KHRDI)
Thank you for your attention !!!

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