East Asian Pharmaceutical Regulatory Symposium 2008
Tokyo International Forum, Tokyo Japan
2008东亚药品监管论坛 日本 东京

April 14-15, 2008

Global Development: China's Perspective and the Role of SFDA - Are We Ready ?

全球药物研发：中国SFDA的视角、作用和责任 – 我们准备好了吗？

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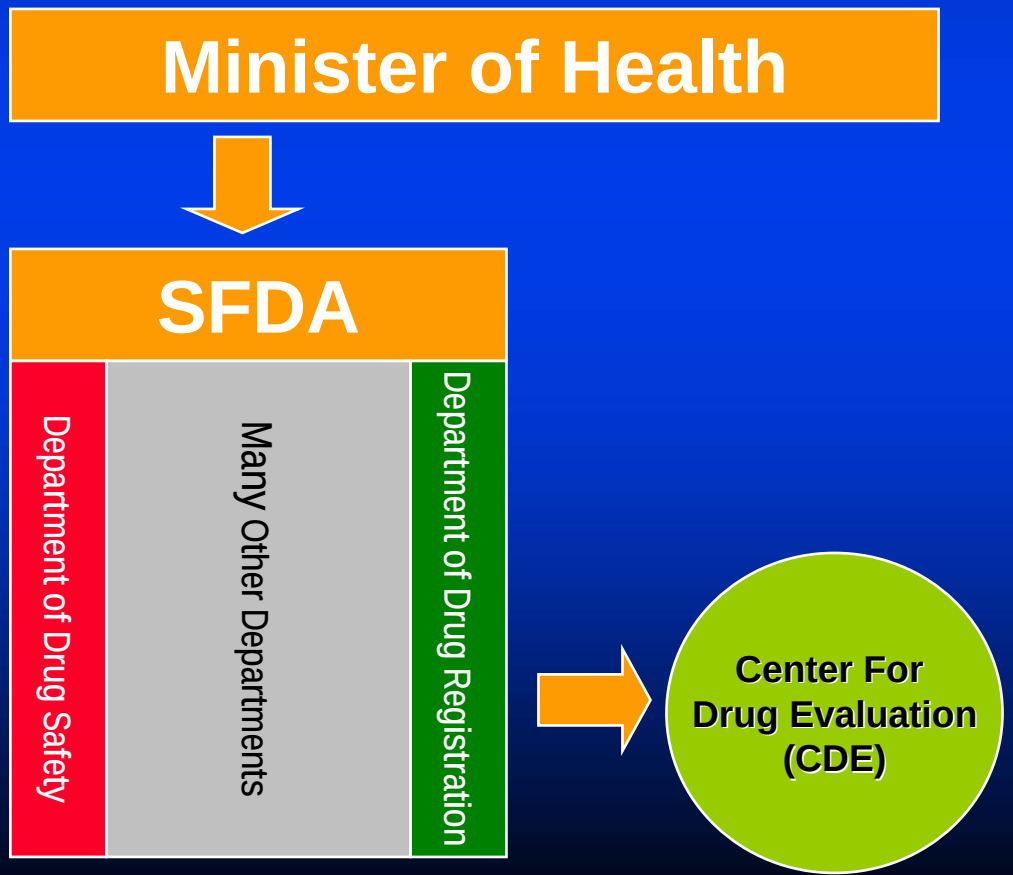
Key Messages

- Global drug development, as part of globalization phenomena, has brought China both opportunities and challenges;
- To carry out our mission in protecting and promoting public health, we needs to actively participate in the process to ensure that the safe and effective treatment that addresses the unmet need of Chinese patients and is with significant public health is readily available to the patients;
- Like many regulatory agencies in the world, we need to develop a risk-based approach to address the issue of insufficient resources. In addition, we need to build a good regulatory/review process to ensure a science-base decision-making process, and also to enhance our scientific knowledge and abilities of our professional staff.

The Department's Responsibility in Relation to Global Drug Development

Organizational Structure



Key Responsibilities

- Final approval of all clinical trials applications in China;
- Final approval of all drug marketing applications in China

Globalization: A double-edged sword

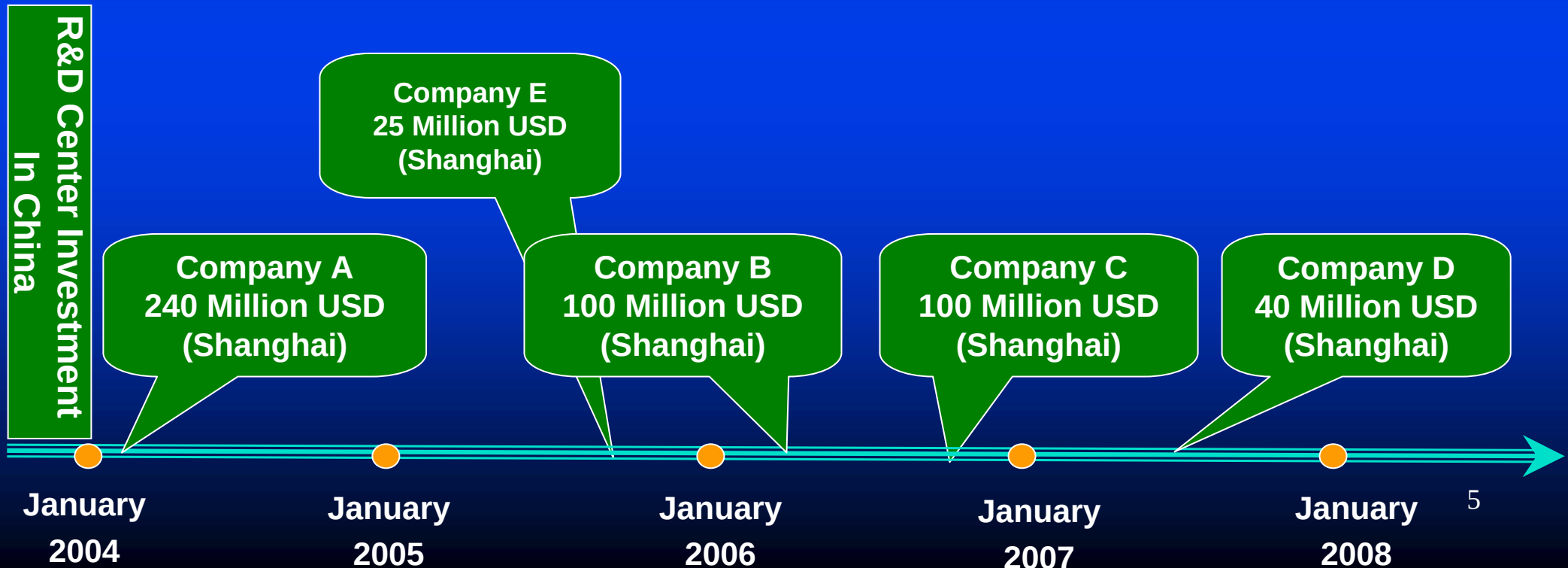
Globalization: A View From US FDA

- Global technology makes mass production of pharmaceutical products possible, but also makes mass production of counterfeit products a reality and the growing currency of organised crime.
- Global Internet technology makes instantaneous communication of important drug safety information possible around the world, but also facilitates instantaneous access to illicit "pharmacies" that are defrauding consumers and that disappear with the push of a "delete" button when a regulator investigates
- The global economy supports new scientific disciplines that are taking us into the molecular world of genetics-based personalised medicine, but also fosters a world in which most people still die of infections for which we have not yet produced simple, effective, available therapies.
- Global transport systems facilitate a world around which we can travel in ways about which our grandparents only dreamed, but also facilitates a world in which any microorganism, any radiation emitting device, or any intentionally contaminated product can be almost anywhere in the world in 24 hours.

Source Data: Dr. Murray M. Lumpkin, Deputy Commissioner, US Food and Drug Administration at 5th Asian Regulatory Conference, Kuala Lumpur, Malaysia, March 11-13, 2008

Global Drug Development: China Perspective (1)

- Global drug development, as part of globalization phenomena, is coming to Asia, the emerging markets in particular. The regulatory bodies in emerging markets need to study it and understand it in order to better carrying out public health mission to their citizens.



Global Drug Development: China Perspective (2)

- Global drug development challenges the regulatory bodies in the emerging markets
  - to have sufficient resources and scientific capacity to conduct a high-quality review and deliver a science-based decision in a consistent and timely manner, and
  - to be more harmonized with the international regulatory standard and practice.
- At the same time, we share the view of Dr. Lumpkin of FDA that "Harmonization does not equal homogenization".

Global Drug Development: China Perspective (3)

- Global drug development also challenges regulatory bodies in mature market. As clinical trial data increasingly come from the emerging market, they will face the same challenge that we are facing now with regard to the applicability of data in their region.
- We anticipate a more closer communication and working relationship between regulatory authorities of mature and emerging markets.

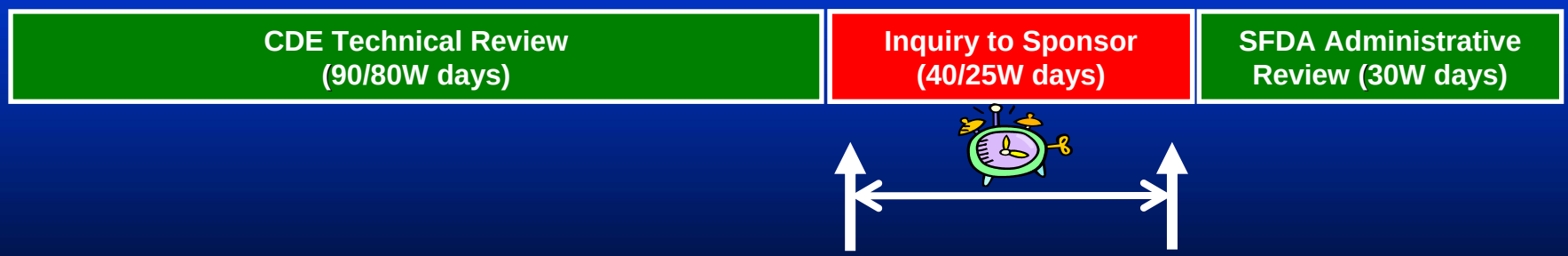
Global Drug Development: China Perspective (4)

- Global drug development also challenges the pharmaceutical industry to build not only local clinical operational excellence but scientific excellence and capacity as well for a better interaction with regulatory bodies.

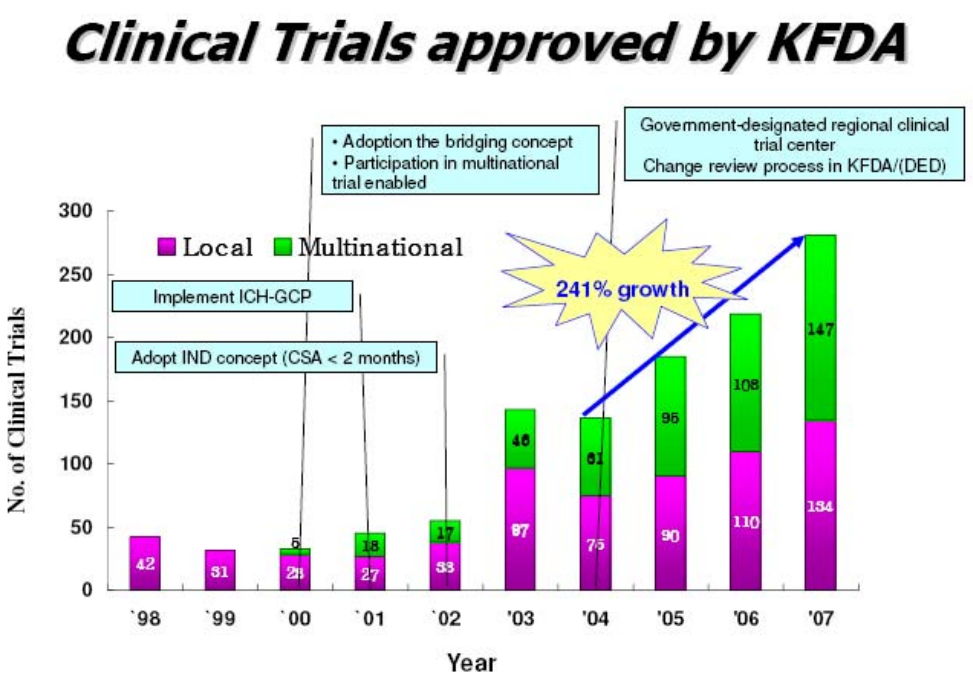
Review Timeline: Role of SFDA vs. Industry

- We understand the concerns over review timeline in SFDA. However, there are always two sides of a story……..

Clinical Trial Application Review and Approval Timeline:



We noted the progress made in Korea and Japan in participating global drug clinical development



Source Data: Dr. In-Sook Park, Drug Evaluation Department, KFDA at 5th Asian Regulatory Conference, Kuala Lumpur, Malaysia, March 11-13, 2008

Current status of Japan

- ICH-E5 guideline (bridging study)
- ICH-E5 Q&A (Q11 for multi-national trials)
- Drug lag problem
- **Basic principles on global clinical trials** (Sep. 28th 2007)
- Rapid increase in planning MCTs (including Asian study)
- NDA approval by MCTs including Asian area

Source Data: Dr. Kazukiko Mori, PMDA at Asian Regulatory Conference, Kuala Lumpur, Malaysia, March 11-13, 2008

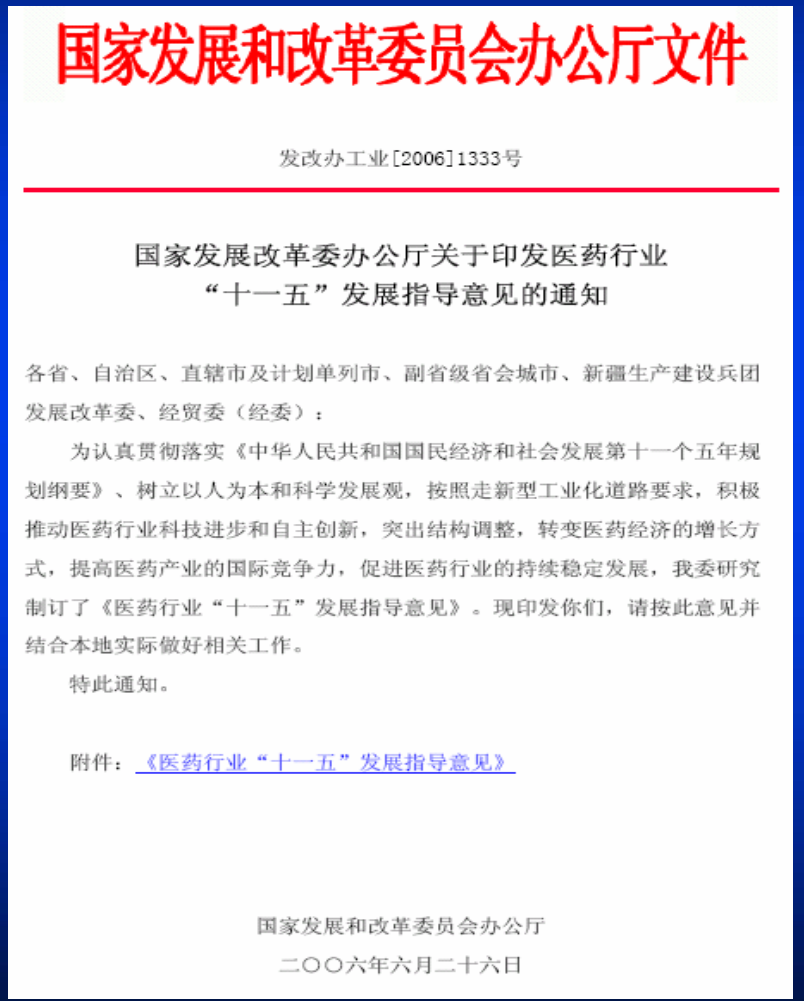
Current Status of New Drug Development in China

- China pharmaceutical industry is transforming from a generic-dominated model to a model that promotes drug innovation. In the last five years ending 2005,
  - 45 drug products approved as new drugs
  - 41 new drug products currently under the NDA review
  - 109 entered into clinical development
- However, R&D investment in China is only 1.06% of total sales in 2005.

Promoting Drug Innovation is a China National Policy

China launches national new drug development plan
http://www.interfax.com/4/374515/news.aspx

"China launched a national new drug development project this year, a government official said at a press conference held in Beijing yesterday. "The national new drug development project aims to produce a new batch of innovative drugs, traditional Chinese medicines and biotech drugs, as well as to provide safe and low-priced drugs to the Chinese people," Sang Guowei, project director, said at the press conference. The project also aims to develop 30 new drugs to treat tumors, cardiovascular disease and hepatitis. As part of the project, China will upgrade 10 existing widely-used drugs, in order to reduce side effects, improve quality and lower prices. Between eight and 10 new drug development platforms will also be set up to improve the country's new drug development system." *(Source: Interfax)*



国家发展和改革委员会办公厅文件

发改办工业[2006]1333号

国家发展改革委办公厅关于印发医药行业“十一五”发展指导意见的通知

各省、自治区、直辖市及计划单列市、副省级省会城市、新疆生产建设兵团发展改革委、经贸委（经委）：

为认真贯彻落实《中华人民共和国国民经济和社会发展第十一个五年规划纲要》、树立以人为本和科学发展观，按照走新型工业化道路要求，积极推动医药行业科技进步和自主创新，突出结构调整，转变医药经济的增长方式，提高医药产业的国际竞争力，促进医药行业的持续稳定发展，我委研究制订了《医药行业“十一五”发展指导意见》。现印发你们，请按此意见并结合本地实际做好相关工作。

特此通知。

附件：《医药行业“十一五”发展指导意见》

国家发展和改革委员会办公厅

二〇〇六年六月二十六日

Newly Revised Provision of Drug Registration (October 1, 2007)

Key Guiding Principles

- To promote drug innovation;
- To focus on unmet medical needs;
- To build a transparent and consistent high quality system;

Process Improvement Related to Global Drug Development:

- 25% Reduction in CSA review time for new drugs
- ICH-CTD format is acceptable
- More flexible in cGMP document requirement
- Simplified sample testing requirement

A Special Review Procedure is Under Development

Issues under discussion to built a quality system

- Consultation Meeting
- Conditional Approval
- Submitting information during the review process

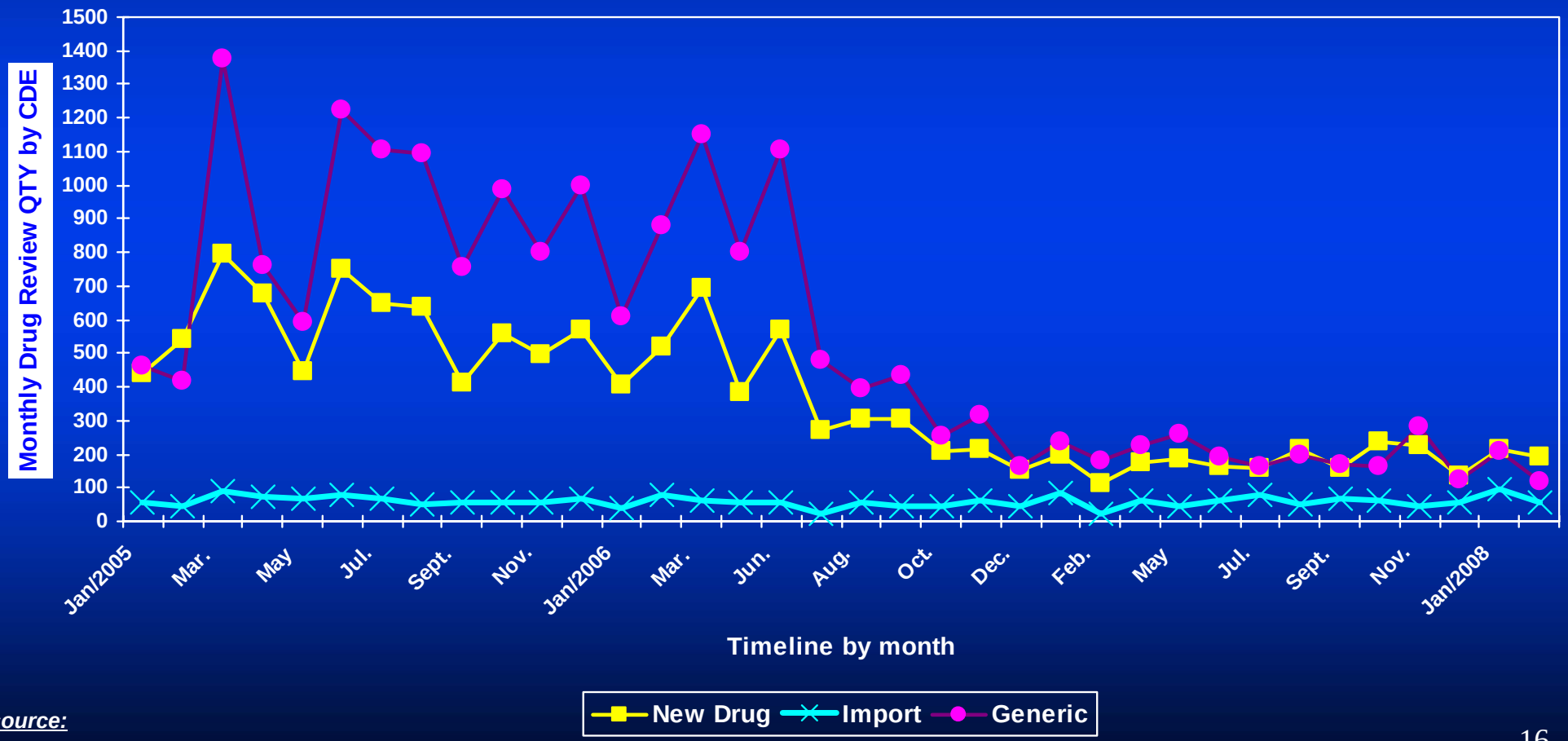
Resource Issue

Chinese SFDA vs. US FDA - Review Capacity and Resource (2005)

	US FDA	Chinese SFDA
Drug Review Responsibility	CDER (Center for Drug Evaluation and Research)	CDE (Center for Drug Evaluation)
New Drugs	20	1,113
Generic Drugs	344	8,075
Number of Employees	1,800	120

Source Data: Dr. Zili LI, Merck & Co, Inc at CMR Conference, December 4, 2007

Number of Drug Applications Filed with SFDA/CDE (Jan-2005 ~ Feb. 2008)



Data Resource:

Monthly drug review updates on CDE website
http://www.cde.org.cn/

Conclusions

- Global drug development has brought China both opportunities and challenges;
- SFDA is committed to promote drug innovation. At the core is to build a quality review system based on GRP;
- A high quality review system will eventually led to a sustained reduction in clinical trial application review time