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Latest Chinese Regulations for Imported Drug Registration: A Comprehensive Guidebook for Foreign Pharmaceutical Companies China Pharmaceutical Guidebook Series (1) (3rd edition)

https://marketpublishers.com/r/GCBAE6576F5EN.html
Date: October 2009
Pages: 152
Price: US$ 750.00 (Single User License)
ID: GCBAE6576F5EN

Abstracts

Preface

China possesses a fourth population in the world and has one of the largest drug markets round the world. By 2006, sales on the Chinese drug market have reached $12 billion dollars, an increase of 3.8 fold over 1998 level. A series of factors, such as an increasingly ageing population, accelerating growth of urban population as well as expansion of healthcare covering urban and rural, will grow the Chinese drug market with a growth rate of 20-25 percent per annum in next five years. China is expected to become the fifth largest drug market in the world by 2010.

Since the reform and open door policy implemented by Chinese authorities in the late 1970s, the door of the Chinese drug market began opening up to the world step by step, which gave a fillip to the imported drugs from overseas pharmaceutical manufacturers and producers. By 2006, sales of imported drugs have shared one fifth on the Chinese drug market. As China joins the World Trade Organization (WTO) and integrates more completely into the global economy, it will further open the door to a lucrative drug market for overseas pharmaceutical companies. More and more overseas pharmaceutical manufacturers and producers expect to enter such drug market and seize a larger part of such drug market. To enter such a lucrative drug market, the first obstacle faced by overseas pharmaceutical manufacturers and producers is how to file the application for their imported drug registration with Chinese pharmaceutical authorities. In China, the process of application and approval for imported drug registration is very complex, because the Chinese pharmaceutical authorities administer

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and control this process by exorbitant administrative measures and regulations, moreover, these exorbitant administrative regulations are variable and lack of transparency. Therefore, a comprehensive and thorough knowledge of the latest Chinese regulations for imported drug registration has been become an essential prerequisite for overseas pharmaceutical manufacturers and producers to achieve a successful application for their products entry into the Chinese drug market. In despite of since the drug registration implemented by the Chinese pharmaceutical authorities on December 1, 2002, its regulatory regime has experienced countless changes, and become increasingly compatible with international standards, in turn, its ongoing consolidation will eventually contribute to a healthier market environment. The Chinese Pharmaceutical authority promulgated the latest “Measures for the Administration of Drug Registration” on July 10 2007, and the latest “Measures” will enter into force since October 1, 2007. These “Measures” provide the latest detailed requirements and procedures of application and approval for imported drug registration. Under such circumstance, Access China Management Consulting Ltd published the China Pharmaceutical Guidebook Series. The aim of this guidebook series is to guide overseas pharmaceutical manufacturers and producers to achieve a successful application and approval for their imported drug registration. This guidebook series are composed of four guidebooks as the following.

- Latest Chinese Regulations for Imported Drug Registration:
A Comprehensive Guidebook for Foreign Pharmaceutical Companies

- Material and Clinical Trial Requirements of Application and Approval for Imported Drug Registration:
A Guidebook of Registration Application for Imported Chemical Drugs

- Material and Clinical Trial Requirements of Application and Approval for Imported Drug Registration:
A Guidebook of Registration Application for Imported Biological Products

- Material and Clinical Trial Requirements of Application and Approval for Imported Drug Registration:
A Guidebook of Registration Application for Imported Traditional Chinese Medicines and Natural Medicines

In this guidebook series, overseas pharmaceutical manufacturers and producers can easily find out every answer that they will meet question during process of application and approval for their imported drug registration. Since the publication of China

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Pharmaceutical Guidebook Series, many executives from overseas pharmaceutical companies have paid attention to this guidebook series, and expect to acquire latest detailed information about Chinese regulations for imported drug registration, so that Access China Management Consulting Ltd completed the third edition to contribute this latest China Pharmaceutical Guidebook Series to overseas pharmaceutical companies. In this latest China Pharmaceutical Guidebook Series, many useful resources of law and regulations, including the Drug Administration Law of the People's Republic of China, the Regulations for Implementation of the Drug Administration Law of the People's Republic of China, the Chinese Good Clinical Practice of Pharmaceutical Products, the Chinese Good Manufacturing Practice for Pharmaceutical Products, the Form of Registration Application for Imported Drug and so on are newly added. After have skimmed through these guidebooks, audience can clearly acquire a comprehensive and thorough knowledge of the latest Chinese regulations for imported drug registration. Access China Management Consulting Ltd hopes this China Pharmaceutical Guidebook Series, based on full and accurate regulations and law, can help guide overseas pharmaceutical manufacturers and producers to achieve a successful application and approval for their imported drug registration in China.

Report Highlights

- An overview of the main responsibilities and organization structure of the SFDA (The State Food and Drug Administration) that is current Chinese pharmaceutical authority at the central level, and takes responsible for application and approval for imported drug registration.
- The comprehensive regulations for imported drug registration in China, from the classification of drugs, definitions relating to application for imported drug registration, the application and approval for imported drugs and repackaging of imported drugs, the supplementary application and re-registration for imported drugs, the clinical investigation for application of imported drug registration to the time limits in drug registration.
- The procedures of application and approval for imported drug registration, including the procedures of the initial application and approval for imported drugs, the supplementary application and approval for imported drugs, and the application and approval for clinical trials relating to imported drugs.
- The significant suggestions for overseas pharmaceutical manufacturers and producers looking to achieve a successful application for their pharmaceuticals registration in China.
- Many useful resources of law and regulations, including the Drug Administration Law of the People's Republic of China, the Regulations for Implementation of the Drug

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Administration Law of the People's Republic of China, the Chinese Good Clinical Practice of Pharmaceutical Products, the Chinese Good Manufacturing Practice for Pharmaceutical Products, the Form of Registration Application for Imported Drug, and so on.

Who should buy this report?
• Companies wishing to enter a lucrative drug market in China.
• Companies interested in understanding the latest Chinese regulations on application and approval for imported drug registration.
• Senior executive officers engaging regulatory and registration affairs for drugs.

Executive Summary

In China, the process of application and approval for imported drug registration is very complex, because the Chinese pharmaceutical authorities administer and control this process by exorbitant administrative measures and regulations, moreover, these exorbitant administrative regulations are variable and lack of transparency. Therefore, a comprehensive knowledge of the latest Chinese regulations for imported drug registration has been become an essential prerequisite for overseas pharmaceutical manufacturers and producers to achieve a successful application for their products entry into the Chinese drug market. This is the first guidebook of the China Pharmaceutical Guidebook Series. It will provide a detailed introduction of the latest Chinese regulations for imported drug registration, and guide overseas pharmaceutical manufacturers and producers to file the application for their drugs with the Chinese pharmaceutical authorities.

Chapter 2 provides an overview of the main responsibilities and organization structure of the State Food and Drug Administration (hereinafter called SFDA) that is current Chinese pharmaceutical authority at the central level, and takes responsible for application and approval for imported drug registration. The aim of this chapter is to give direction of gateway for application of imported drug registration. Chapter 3 addresses the comprehensive regulations for imported drug registration in China, from the classification of drugs, definitions relating to application for imported drug registration, the application and approval for imported drugs and repackaging of imported drugs, the supplementary application and re-registration for imported drugs, the clinical investigation for application of imported drug registration to the time limits in drug registration. Chapter 4 introduces the procedures of application and approval for imported drug registration, including the procedures of the initial application and

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approval for imported drugs, the supplementary application and approval for imported drugs, and the application and approval for clinical trials relating to imported drugs. The guidebook concludes in chapter 5 by highlighting the significant suggestions for overseas pharmaceutical manufacturers and producers looking to achieve a successful application of their drug registration in China. The appendices in chapter 6 include the Drug Administration Law of the People's Republic of China, the Regulations for the Drug Administration Law of the People's Republic of China, the Chinese Good Clinical Practice of Pharmaceutical Products, the Chinese Good Manufacturing Practice for Pharmaceutical Products, the Form of Registration Application for Imported Drug, references, a useful resources of URL, author's biography, and description of Access China Management Consulting Ltd. After have skimmed through this guidebook, audience can be clearly aware of the latest Chinese regulations for application and approval of imported drug registration. For the detailed requirements of material items and clinical trial for application and approval of imported drug registration of various categories, such as chemical drugs, biological products, traditional Chinese medicines and natural medicines, audience can learn from various fascicles of the China Pharmaceutical Guidebook Series.

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