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China Pharmaceutical Guidebook Series (2) 2013 Edition Material and Clinical Trial Requirements of Application and Approval for Imported Drug Registration: A Guidebook of Registration Application for Imported Chemical Drugs

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Abstracts

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 2012, sales of imported drugs have shared one fourth 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 of 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 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. Access China Management Consulting Ltd published the China Pharmaceutical Guidebook Series: 2013 Edition. The aim of this guidebook series is to guide overseas pharmaceutical manufacturers and producers to achieve a successful application and

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approval for their imported drug registration. This guidebook series are composed of four guidebooks as the following.

Latest Chinese Regulations for Imported Drug Registration: 2013 Edition
A Comprehensive Guidebook for Foreign Pharmaceutical Companies

Material and Clinical Trial Requirements of Application and Approval for Imported Drug Registration: 2013 Edition
A Guidebook for Application of Imported Chemical Drugs Registration

Material and Clinical Trial Requirements of Application and Approval for Imported Drug Registration: 2013 Edition
A Guidebook for Application of Imported Biological Product Registration

Material and Clinical Trial Requirements of Application and Approval for Imported Drug Registration: 2013 Edition
A Guidebook for Application of Imported Traditional Chinese Medicine and Natural Medicine Registration

This is the second guidebook of the China Pharmaceutical Guidebook Series. It will provide a detailed introduction of SFDA's requirements for materials and clinical trials of application and approval for imported chemical drug registration, including radioactive pharmaceuticals.

Chapter 2 provides an overview of the classification of drug registration that is formulated by the SFDA. To understand this classification of drug registration only is the first step for an application of chemical drug registration, because applicant must file the application in accordance with this classification of drug registration. Chapter 3 addresses the material items for application of chemical drug registration. The SFDA collected all materials for application of chemical drug registration into four categories and 32 items. There are the summary materials, the research materials of pharmaceutics, the research materials of pharmacology and toxicology, and the materials of clinical investigation. For administrative requirement of chemical drug registration, the SFDA provides the detailed explanations for many material items and precedes the ordinal numeral for each material item. When an application is filed, the SFDA will request applicant to submit the materials for application of chemical drug registration of various categories in accordance with the material item's ordinal numeral. Therefore, to understand the material items is the second step for application

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of chemical drug registration. Chapter 4 introduces the requirements of material items for application of chemical drug registration in terms of the form of material items and their explanatory notes. The form of material items represents the current requirements of material items for application of chemical drug registration stipulated by the SFDA. The explanatory notes further explain the requirements of material items for various categorical chemical drugs. To understand the contents of this section is a core for application of chemical drug registration. The application of imported chemical drug registration must accord with the material items prescribed by the form of material Items and the explanatory notes to submit materials. Chapter 5 addresses the requirements of clinical trial for application of chemical drug registration. There are two parts, i.e. the general requirements of clinical trial and the special requirements of clinical trial for imported chemical drug. Chapter 6 introduces the material and clinical trial requirements for application of radioactive pharmaceuticals, from the definitions, the requirements of material items, the explanatory notes of material items to the requirements of clinical trial. The guidebook concludes in chapter 7 by highlighting the significant suggestions for overseas pharmaceutical manufacturers and producers looking to achieve a successful application for their chemical drug registration in China. Last, the appendices in chapter 8 include the Drug Administration Law of the People's Republic of China, the Regulations for Implementation of Drug Administration Law of the People's Republic of China, the Chinese Good Clinical Practice of Pharmaceutical Products, the Application Form of Imported Drug Registration, references, and description of Access China Management Consulting Ltd. After have skimmed through this guidebook, audience can be clearly aware of the latest Chinese regulations on requirements of the materials and the clinical trials for application of imported chemical drug registration. For the detailed pathway and procedure for application and approval of imported drug registration, audience can learn from the first guidebook of the China Pharmaceutical Guidebook Series (2013 Edition) ---- Latest Chinese Regulations for Imported Drug Registration: A Comprehensive Guidebook for Foreign Pharmaceutical Companies.

Report Highlights

An overview of the classification of drug registration formulated by the SFDA (The State Food and Drug Administration in China).

The material items for application of drug registration.

The requirements of material items for application of drug registration.

The requirements of clinical trial for application of drug registration.

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The material and clinical trial requirements for application of radioactive pharmaceuticals

The significant suggestions for overseas pharmaceutical manufacturers and producers looking to achieve a successful application for their chemical drug 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 Administration Law of the People’s Republic of China, the Chinese Good Clinical Practice of Pharmaceutical Products, the Form of Registration Application for Imported Drug, and so on.

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