+44 20 8123 2220
info@marketpublishers.com

China Pharmaceutical Guidebook Series (4) 2013 Edition 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

https://marketpublishers.com/r/C91EB29E3C2EN.html
Date: May 2013
Pages: 118
Price: US$ 750.00 (Single User License)
ID: C91EB29E3C2EN

Abstracts

The traditional medicines in Orient, especially, the traditional Chinese medicines are always regarded by occidental as mysterious medicines. Until today not only the chemical composition of traditional Chinese medicines almost can not been expressed by a precise chemical structural formula, but also the indications of the majority of traditional Chinese medicines still can not been clearly described by the modern medical terminologies. How the Chinese drug authorities to administer the registration application for such mysterious traditional Chinese medicines? This is the fourth guidebook of the China Pharmaceutical Guidebook Series. It will provide a detailed introduction of the Chinese pharmaceutical authorities' requirements for materials and clinical trials of application and approval for imported traditional Chinese medicine. The Chinese pharmaceutical authorities collect the traditional Chinese medicines and the natural medicines into a category for registration application. Therefore, this guidebook will provide not only the introduction for registration application of imported traditional Chinese medicines but for the natural medicines.

In China, like in other Western countries, the pharmaceutical authority -- China Food and Drug Administration (hereafter called CFDA) requests applicant to submit complicate and reliable materials for application of medicine registration. The CFDA stipulated the classification of medicine registration in order to administer the application of traditional Chinese medicine and natural medicine registration. At the same time, the

+44 20 8123 2220
info@marketpublishers.com

CFDA collected the materials for application of traditional Chinese medicine and natural medicine registration into four categories and 33 items in accordance with various medicine categories. When an application of traditional Chinese medicine and natural medicine registration is filed, the CFDA will request applicant to not only submit designated material items in accordance with prescribed category of traditional Chinese medicines and natural medicines to apply for registration, but also conduct the clinical trials for certain categorical traditional Chinese medicines and natural medicines.

Chapter 2 provides an overview of the classification of medicine registration that is formulated by the CFDA. To understand this classification of medicine registration only is the first step for an application of traditional Chinese medicine and natural medicine registration, because applicant must file the application in accordance with this classification of medicine registration. Chapter 3 addresses the material items for application of traditional Chinese medicine and natural medicine registration. The CFDA collected all materials for application of traditional Chinese medicine and natural medicine registration into four categories and 33 items, i.e. 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 traditional Chinese medicine and natural medicine registration, the CFDA provides the detailed explanations for many material items and precedes the ordinal numeral for each material item. When an application is filed, the CFDA will request applicant to submit the materials for application of traditional Chinese medicine and natural medicine 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 of traditional Chinese medicine and natural medicine registration. Chapter 4 introduces the requirements of material items for application of traditional Chinese medicine and natural medicine 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 traditional Chinese medicine and natural medicine registration stipulated by the CFDA. The explanatory notes further explain the requirements of material items for various categorical traditional Chinese medicines and natural medicines. To understand the contents of this section is a core for application of traditional Chinese medicine and natural medicine registration. The application of imported traditional Chinese medicine and natural medicine 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 traditional Chinese medicine and natural medicine registration. There are two parts, i.e. the general requirements of clinical trial and the special requirements of clinical trial for imported traditional Chinese medicines and natural medicines. The

+44 20 8123 2220
info@marketpublishers.com

guidebook concludes in chapter 6 by highlighting the significant suggestions for overseas pharmaceutical manufacturers and producers looking to achieve a successful application for their traditional Chinese medicine and natural medicine registration in China. Last, the appendices in chapter 7 include 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, 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 traditional Chinese medicine and natural medicine 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 - Latest Chinese Regulations for Imported Drug Registration: A Comprehensive Guidebook for Foreign Pharmaceutical Companies.

Report Highlights

An overview of the classification of medicine registration formulated by the CFDA (China Food and Drug Administration in China).

The material items for application of medicine Registration.

The requirements of material items for application of medicine registration.

The requirements of clinical trial for application of medicine registration.

The significant suggestions for overseas pharmaceutical manufacturers and producers looking to achieve a successful application for their traditional Chinese medicine and natural medicine 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.

+44 20 8123 2220
info@marketpublishers.com

Contents

+44 20 8123 2220
info@marketpublishers.com

+44 20 8123 2220
info@marketpublishers.com

About

China possesses a fourth population in the world and has one of the largest drug markets round the world. By 2012, sales on the Chinese drug market have reached RMB 926.1billion (about US$147 billion) reported by the «2012: Report of China Pharmaceutical Market» published by Chinese Academy of Social Sciences. It is estimated that it will exceed RMB 1,000 billion by 2013. According to the report “China Pharmaceutical Guidebook Series (4) 2013 Edition 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” by Access China Management Consulting, 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 over 20 percent per annum in next three years. China is expected to become the second largest drug market in the world by 2015.

Since the reform and open door policy implemented by the 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. 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

+44 20 8123 2220
info@marketpublishers.com

consolidation will eventually contribute to a healthiermarket environment. The Chinese Pharmaceutical authority promulgated the last “Measures for the Administration of Drug Registration” on July 10 2007, and the last “Measures” entered into force since October 1, 2007. However, the practical operations for application and approval of imported drug registration have been constantly changed, because the amendment of “Measures” is sluggish. Under such circumstance, 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 approval for their imported drug registration.

+44 20 8123 2220
info@marketpublishers.com

I would like to order

Product name: China Pharmaceutical Guidebook Series (4) 2013 Edition 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

Product link: https://marketpublishers.com/r/C91EB29E3C2EN.html

Price: US$ 750.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:
info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page https://marketpublishers.com/r/C91EB29E3C2EN.html

To pay by Wire Transfer, please, fill in your contact details in the form below:

First name:
Last name:
Email:
Company:
Address:
City:
Zip code:
Country:
Tel:
Fax:
Your message:

**All fields are required

Custumer signature _____

Please, note that by ordering from marketpublishers.com you are agreeing to our Terms & Conditions at https://marketpublishers.com/docs/terms.html

+44 20 8123 2220
info@marketpublishers.com

To place an order via fax simply print this form, fill in the information below and fax the completed form to +44 20 7900 3970