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美国关于中药法律法规的历史沿革及展望

投稿时间: 2013-04-22 最后修改时间: 2013-04-22 点此下载全文

引用本文: 陈涛. 美国关于中药法律法规的历史沿革及展望[J]. 全球科技经济瞭望, 2013, 28(7):37~41

摘要点击次数: 167

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中文摘要:中医药在美国只是相对西药独立存在的多种传统医药的一种。为与西医进行区分,美国人将这些不同的医学统一称为补充与替代医学。迄今为止,美国尚无对中药管理的专门法 律法规,对中药的要求分散在不同的法律法规中。2004 年,美国颁发了《植物药物产品指南》,为以植物药为主的中药进入美国主流医药市场开启了一扇大门。我国中医药企业应充分利 用《植物药物产品指南》,选择能够在较短时间内满足 FDA 相关要求并具有显著疗效的中药产品,完成中药在美国的新药申请并尽快上市。

中文关键词:美国;中药;补充与替代医学

Development of US Federal Laws and Regulations Regarding Chinese Herbal Medicine: History and Outlook

Abstract: Chinese medicine, categorized as the complementary and alternative medicine in the United States, is one of many kinds of traditional medicines. By far, no specific law or regulation is released in U.S. particularly aimed at the Chinese herbal medicine (CHM). The legal restriction and management for CHM were scattered in other different laws and regulations. The Guide for Botanical Drugs released in 2004 has opened a door for Chinese medicine into the American mainstream pharmaceutical market. The Chinese medicine enterprises should make full use of the guide, selecting some traditional Chinese medicine products that have remarkable curative effects and meet the FDA requirements, to complete their new drug applications in the United States and push them to the American pharmaceutical market as soon as possible. This article mainly studied the laws, regulations and policies regarding CHM published by US federal government and the Food and Drug Administration, analyzed their influence on CHM development and investigated the developing trend of CHM in the U.S..

 $\verb|keywords:United States|; Chinese herbal medicine; complementary and alternative medicine|\\$

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技术支持: 北京勤云科技发展有限公司