JYBZ13000812

【正本】

中华人民共和国
People's Republic of China

进口药品包装用材料和容器注册证
IMPORT PACKAGE MATERIAL FOR DRUGS LICENSE

注册证号：进药包字J20140028
LICENSE NO.

根据《中华人民共和国药品管理法》和《药品包装用材料和容器管理办法》（暂行）的规定，兹批准下述公司的下述药品包装用材料和容器注册，允许进口使用。

According to the Drug Administration Law of P. R. of China and the Drug Package Material Administration Provisions, the following package material for drugs produced by the following company have been approved and registered, Importation are authorized thereby.

产品名称 Generic name：聚氯乙烯/聚三氟氯乙烯/聚氯乙烯固体药用复合硬片

规　格 Specification：-----

包装规格 Package size：-----

公司名称 Company：Kloeckner Pentaplast Schweiz AG

地　址 Address：Industriegebiet Heiligenroth ,D56401 Montabaur ,Germany　国家 Country：德国

生产厂 Manufacturer：Kloeckner Pentaplast Schweiz AG

地　址 Address：Sportweg 38,CH-3097 Liebefeld/Bern,Switzerland　国家 Country：瑞士

备　注 Remarks：
1. 本证有效期至 Valid Until 2019 年 6 月 3 日
2. 本品进口检验标准 Testing Specifications：JBB-0024-2013
3、原注册证（进药包字J20080008）注销

国家食品药品监督管理总局
China Food and Drug Administration

2014 年 6 月 4 日

进口药品注册专用章

No. 1301057

注　意　事　项

POINTS OF ATTENTION

1. 本证是国家食品药品监督管理总局核发的批准所列品种进口中国和销售使用的法定文件，分为“正本”和“副本”。未取得本证的品种一律不得进口，销售和使用。

   This license,both in form of Blue paper or Green paper, is the legal document issued by China Food and Drug Administration indicating the authorization granted to a given production specified therein for its importation,marketing and sales in China. No importation. Marketing and sales of any productions are permitted without this license.

2. 进口产品的包装必须注明本证规定的中文产品名称，注册证号以及所列“公司”和“生产厂”名称，地址。包装，标签与注册证不一致的，一律不得进口。注册证号有变化的必须注册新注册证号，原注册证号同时作废。

   It should be indicated clearly, on the packing and labeling ,the name of the product in Chinese , the license number , and the name and address of the company and/or manufacturer . No importation is permitted , in case of any divergence from that specified in the license. The new license number should be used ,if license number is changed ,whereas the old one becoming invalid simultaneously.

3. 本证所列公司指对本注册品种拥有上市权的公司，并对该品种质量负法律责任；生产厂指本注册品种的具体生产工厂。

   The said company hereby refers to the marketing authorization holder , and , is holding legal responsibility for the quality assurance ; whereas the manufacturer refers to the specific plant , in which the product is produced.

4. 本证自核发之日起五年有效，必须在失效期6个月前提出换证申请，经审核批准的发给新的注册证号。超过该证有效期提出换证的，按新申报注册品种处理。

   The license is valid for a five years from the issuing date . An renewal application must be submitted 6 months prior to its expiry . A new license number will be given , once the application is approved . Any application submitted beyond the valid date will be regarded as a new application.

5. 进口口岸报验时，必须出示本证“正本”或“副本”原件。

   When applying to customs at the port of entry ,the original blue or green license should be presented.

6. 本证请妥善保管，遗失或损坏的不予补发。

   The license should be well kept and no re-issue is made in case of loss and/or damage.

7. 本证所载项目内容有变化的。应及时申报，经批准后方可更改。

   The license should be timely submitted , if there is any changes in contents specified in the license . The proposed change is seen valid after its approval.

8. 违反中华人民共和国药品管理法律、法规的，其注册证将被注销。

   The license shall be cancelled in case of any violation of laws and regulations of P.R.of China governing drug administration.

【副本】

中 华 人 民 共 和 国
People's Republic of China

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IMPORT PACKAGE MATERIAL FOR DRUGS LICENSE

注册证号：进药包字J20140028
LICENSE NO.

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Generic name

规　　格：
Specification

包装规格：
Package size

公司名称：Kloeckner Pentaplast Schweiz AG
Company

地　　址：Industriegebiet Heiligenroth ,D56401 Montabaur ,Germany　国家：德国
Address　Country

生 产 厂：Kloeckner Pentaplast Schweiz AG
Manufacturer

地　　址：Sportweg 38,CH-3097 Liebefeld/Bern,Switzerland　国家：瑞士
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国家食品药品监督管理总局
China Food and Drug Administration

2014 年 6 月 4 日

CHINA FOOD AND DRUG ADMINISTRATION 国家食品药品监督管理总局 进口药品注册专用章

No. 1301571

注　意　事　项

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