1994

进口药品品种目录

THE OFFICIAL LISTING OF IMPORT DRUGS IN THE PEOPLE'S REPUBLIC OF CHINA

VOLUME V

中华人民共和国
卫生部药政管理局

BUREAU OF DRUG ADMINISTRATION AND POLICY
MINISTRY OF PUBLIC HEALTH · BEIJING

进口药品品种目录（V）
THE OFFICIAL LISTING OF IMPORT DRUGS IN THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国
卫生部药政管理局
BUREAU OF DRUG ADMINISTRATION AND POLICY
MINISTRY OF PUBLIC HEALTH
THE PEOPLE'S REPUBLIC OF CHINA
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说　明

1. 《进口药品品种目录》第五册包括 **1994** 年期间已获批《注册证》从 X940001-X940445 号的品种以及从 XT94001-XT94015 号的台湾产品。已获得换证的品 种按新序号执行。
2. 本目录药品排列顺序按《注册证》序号排列。
3. 中文药名索引按中文首字笔划数目顺序排列。英文药名索引按英文字母顺序排列。
4. 本目录资料根据申请厂商填写的申请表及中华人民共和国卫生部核发的《注册证》内容编写。
5. 每个《注册证》只对该证载明的品名和生产国家、厂家有效。

EXPLANATORY NOTES

1. "THE OFFICIAL LISTING OF IMPORT DRUGS IN THE PEOPLE'S REPUBLIC OF CHINA [VOLUME V]" (hereinafter referred to as the "LISTING") includes the drug preparations which have obtained the "Registration Certificate" listed from X940001-X940445 and XT94001-XT94015 (TAIWAN products) during **1994**. The drugs with renewed registration are effective by their new ordinal numbers of certificates.
2. The "LISTING" is arranged according to the ordinal numbers of "Registration Certificate".
3. The Chinese index of drug names is arranged in strokes number of the first Chinese character. The English index of drug names is arranged in English alphabetical order.
4. All data in the "LISTING" originate from the contents of the application forms submitted by the applicants and the "Registration Certificate" issued by the Ministry of Public Health of the People's Republic of China.
5. Every "Registration Certificate" is applicable only to the indicated drug, the country and manufacturer as stated therein.

中华人民共和国卫生部
关于发布《进口药品管理办法》的通知（摘录）
1990年11月2日

1. 经商海关总署，本“办法”自一九九一年元月一日起执行。对以往公布的有关进口药品的管理规定，凡与本“办法”有抵触的，一律按本“办法”执行。
2. 卫生部核发的《进口药品许可证》自本办法执行之日起改为《进口药品注册证》，有效期为三年。国外厂商已取得有效期为四年的“许可证”，仍按原有效期执行。
3. 今后对进口药品一律凭卫生部核发的《进口药品注册证》复印件或《一次性进口药品批件》报验。

ANNOUNCEMENT OF THE "PROVISIONS FOR MANAGEMENT OF IMPORT DRUGS" by the Ministry of Public Health of the People's Republic of China (Extracts)
November 2, 1990

1. It has been decided through consultation with the Customs General Administration that the "Provisions for Management of Import Drugs" shall come into force on Jan. 1 of 1991. Any stipulations of management concerning import drug promulgated formerly contrary to this "Provisions" must be subordinated to the latter.
2. The "Import Drug Permit" issued by the Ministry of Public Health of the People's Republic of China shall be renamed as the "Registration Certificate of Import Drug" when the "Provisions" comes into force. The "Certifcate" is valid for 3 years. The "Permit(s)" with validity period of 4 years held by foreign manufacturing enterprise(s) shall continue to be effective until its (their) expiry date (s).
3. Import drug must undergo coastal analysis against the copy of the "Registration Certificate for Import Drug" or "Registration Certificate for Import Drug Valid for Only Once" issued by the Ministry of Public Health of the People's Republic of China.

—For English version: In case of discrepancy, the original version in Chinese shall prevail.

进口药品管理办法(摘录)
1990年11月2日

第一章　总则

第一条　为加强对进口药品的监督管理,保证进口药品的质量和安全有效,根据《中华人民共和国药品管理法》及其它有关法律、法规的规定,特制定本办法。

第二条　国务院卫生行政部门主管全国进口药品的监督管理工作。各省、自治区、直辖市卫生厅(局)负责其辖区内的进口药品的监督管理工作。

第三条　进口药品必须经口岸药品检验所法定检验。卫生部授权的口岸药品检验所(以下简称口岸药检所)代表国家对进口药品实施法定检验。

中国药品生物制品检定所负责对口岸药检所进行技术指导和有争议的检验结果的裁决。

第四条　进口药品必须是国内医疗需要的安全有效的品种。

第二章　进口药品的注册

第五条　国家对进口药品实行注册制度。凡进口的药品,必须具有卫生部核发的《进口药品注册证》。《进口药品注册证》对该证载明的品名和生产国家、厂商有效。

医疗特需或国内生产不能满足医疗需要,但又尚未取得《进口药品注册证》的品种,进口单位需报经卫生部审查批准,发给《一次性进口药品批件》。《一次性进口药品批件》只对该批件载明的品名、生产厂商、数量、期限和口岸药检所有效。

第六条　申请《进口药品注册证》的国外生产厂商或经营代理商须提出申请,并填写"进口药品注册证申请表"一式两份,连同要求的资料,报送卫生部药政局。特殊需要一次性进口的,由国内进口单位提出申请,连同要求的资料报送所在省、自治区、直辖市卫生厅(局)初审后,转报卫生部药政局批准。

第七条　申请《进口药品注册证》需报送以下资料:

1. 药品生产国卫生当局签发的批准该药品生产、销售、出口及符合药品生产质量管理规范(GMP)的证明文件,且附中文译本;

2. 专利品证明文件;

3. 药品说明书及中文译本;

4. 技术资料;

(1)药品处方,包括活性成份、辅料的名称(包括非专利名、商品名和化学名)和用量等;

(2)药品生产方法;

(3)药品质量标准及检验方法,并附中文译文;

(4)药品的药理、毒理实验摘要及文献资料;

(5)药品的临床资料,包括适应症、剂量、给药途经、与其它药物的配伍作用、毒副反应、禁忌症和注意事项等;

(6)药品的稳定性实验资料。

5. 药品实样;

6. 包装材料和包装样本。

第八条　申请《进口药品注册证》所附质量标准若为药典或生物制品规程未收载的企业标准，生产厂商应提供三批样品，送卫生部药政局指定的口岸药检所进行药品及其质量标准的复核，符合要求，方可进行审查。

第九条　首次进口的药品需在中国境内进行临床试验或验证。

第十条　《进口药品注册证》自签发之日起有效期三年。到期时，国外生产厂商或经营代理商可申请换证，但必须在注册证失效前六个月向原发证机构提出，并附生产国批准该药品生产和销售的文本、说明书和质量标准等资料，经审核同意方可换证。进口药品质量标准、生产工艺、适应症、说明书等资料若有修改的，生产厂商应及时向卫生部药政局补报有关资料，以备审核。

……（略）

第七章　附　则

第二十五条　依据本办法，卫生部核发《进口药品注册证》，口岸药检所实施检验和对外出证，按照有关规定收费。

第二十六条　麻醉药品、精神药品、放射性药品的进口，按国务院颁发的《麻醉药品管理办法》、《精神药品管理办法》和《放射性药品管理办法》办理。

第二十七条　进口人血清白旦白及卫生部特许进口的血液制品，必须按有关规定报经卫生部审核批准后，方可组织进口。

第二十八条　本办法所指的国际通用药典是《美国药典》、《英国药典》、《日本药局方》和《欧洲药典》。

第二十九条　本办法由卫生部负责解释。

第三十条　本办法自 1991 年 1 月 1 日起执行。

Provisions Governing Import Drugs Promulgated on Nov. 2, 1990 by the Ministry of Public Health of the People's Republic of China

CHAPTER 1　GENERAL PROVISIONS

Article 1

With a view to strengthening the control and supervision of import drugs and guaranteeing their quality, safety and efficacy, these provisions are established according to the" Drug Administration Law of the People's Republic of China " and other acts, regulations.

Article 2

The health administrative agency of the State Council of the People's Republic of China is the competent authority for the control and supervision of import drugs. The Public Health Department (Bureau)of provinces, autonomous regions, and municipalities directly under the central government are responsible for the control and supervision of drugs imported within their own jurisdiction.

Article 3

Import drugs must undergo official analysis conducted by the Coastal Institutes for Drug Control (hereafter referred as Coastal Institutes). The Coastal Institutes are authorized by the Ministry of Public Health of the People's Republic of China to conduct official analysis for imported drugs on behalf of the government.

The National Institute for the Control of Pharmaceutical and Biological Products is responsible for the technical guidance for Coastal Institutes and the adjudication of disputed analytical results.

Article 4

Import drugs must be those varieties that are safe, effective, and meet the requirments of domestic clinical practice.

CHAPTER 2 REGISTRATION OF IMPORT DRUG

Article 5

A Registration system for the control of import drugs is enacted by the country. Import drug must have a "registration certificate for import drug"issued by the Ministry of Public Health of the People's Republic of China. The registration certificate is applicable only to the drug, the country, and the manufacturer as stated therein.

For a variety of drug with no registration certificate which is specially required in clinic practice or cannot totally be supplied by domestic production, an application must be submitted to the Ministry of Public Health of the People's Republic of China by the importing unit and a"registration certificate valid for only once"will be granted by the Ministry if it is approved. This certificate is applicable only to the drug, the manufacturer, the quantity, the time limit and the Coastal Institute specified therein.

Article 6

When a"registration certificate for import drug"is applied for by a foreign manufacturer or its agent , an application form shall be completed in duplicate and submitted, with all data and documents as so required, to the Bureau of Drug Administration and Policy of the Ministry of Public Health of the People's Republic of China. A"registration certificate for import drug valid for only once"of a specially wanted drug should be applied for by the domestic importing unit and all the data and documents so required shall be submitted to the Public Health Department (Bureau) in the province, autonomous region, or municipality directly under the central government for preliminary examination and then transferred to the Bureau of Drug Administration and Policy of the Ministry of Public Health of the People's Republic of China, for approval.

Article 7

Following data and documents shall be submitted when applying for the registration certificate.

1. Original and Chinese translation copy of the certificate issued by the health authority of the exporting country ratifying the production, marketing , and exportation of the drug concerned, as well as GMP inspection report of the exporting country;

2. Letter of patent;

3. Data sheet and their Chinese translation;

4. Technical informations;

1) Formula, names (including non — proprietary name, trade name, chemical name) of active-ingredients, and adjuvants and dosages;

2) Brief description of its production process;

3) Specifications and quality control methods of the drug(s) and their Chinese translations;

4) Abstracts of its pharmacological and toxicological experiments, and literature informations;

5) Clinical data, including indications, dosages, route of administration, compatibility with other drugs, adverse and side—effects, contraindications, and precautions;

6) Data on its stability studies;

5. Samples of the drug(s); and

6. Samples of packaging, and labelling material.

Article 8

In the application of a "registration certificate for import drug" if the attached specifications is not included in a Pharmacopoeia or in the "Provisions of Biological Products" i. e. a standard of the manufacturer's, then three batches of sample should be submitted to the Coastal Institute assigned by the Bureau of Drug Administration and Policy of the Ministry of Public Health of the People's Republic of China for inspection. Its examination can be continued only when the standard is proved to be acceptable.

Article 9

Drug(s) imported for the first time shall be subject to clinical study or validation in the territory of China.

Article 10

"Registration Certificate for Import drug" is valid for 3 years as of its issuance. Renewal of the registration certificate may be applied for by foreign manufacturer and their agent six months before its expiration, and in this case, a certificate issued by the exporting country ratifying the production and marketing as well as documents such as data sheet and specifications should also be attached, the new certificate shall be issued if renewal is approved.

If revisions have been made on specifications, production process, indications, data sheet, etc. the revised documents should be submitted timely to the Ministry of Public Health of the Peoples's Republic of China for reexamination.

……(Be omitted)

CHAPTER 7 SUPPLEMENTARY ARTICLE

Article 25

Charges for the issuance of "registration certificate for import drug" by the MPH. , PRC. , and for the analysis and issuance of certificate to foreign country by Coastal Institute shall be collected in accordance with relevant provisions.

Article 26

Narcotic drugs, psychotropic drugs, radiopharmaceuticals shall be imported according to "Regulations for the Control of Narcotic Drugs", "Regulations for the Control of Psychotropic Drugs", and "Regulatioms for the Control of Radiopharmaceuticals" promulgated by the State Council of the People's Republic of China.

Article 27

Human serum albumin and blood preparations specially permitted by MPH. , PRC. , may only be imported after approval by the MPH. PRC. in accordance with relevant regulations.

Article 28

The phrase "pharmacopoeias generally used in international commerce" used in this document refers to "United States Pharmacopoeia", "British Pharmacopoeia", "Japanese Pharmacopoeia" and "European Pharmacopoeia".

Article 29

The Ministry of Public Health of the People's Republic of China is responsible for the interpretation of the provisions.

Article 30

These provisions shall come into force on Jan. 1 of 1991.

(Translated by the Bureau of Drug Administration and Policy of the Ministry of Public health . In case of discrepancy , the original version in Chinese shall prevail.)

换发《进口药品注册证》的规定

1991 年 6 月

第一条 根据《进口药品管理办法》第十条的要求，特制订本规定。

第二条 换发《进口药品注册证》必须由生产厂家或其代理商自愿向卫生部药政管理局申请，并须在原注册证失效前六个月提出。

第三条 申请换发《进口药品注册证》需填写申请表一式两份，并报送以下资料：

1、生产国卫生当局批准该药品生产和销售的文件；

2、该药品的使用说明书；

3、取得《进口药品注册证》后，该产品质量标准、生产工艺若有修改的，应报送新的质量标准。

以上资料均需中文译本。

第四条 卫生部药政管理局根据下述原则处理换证申请：

1、凡疗效肯定、质量可靠，并且临床或国内医药生产需要的品种，可予换发《进口药品注册证》；

2、凡其疗效不确或对其疗效有争议品种，需重新安排临床验证，并进行再评价后，方可决定是否换发《进口药品注册证》；

3、凡国内已有生产并能满足医疗需要的品种，且质量不低于国外产品，即不再换发《进口药品注册证》。

第五条 未获得换证的品种，从原《进口药品许可证》或《进口药品注册证》失效之日起，国内进口单位不得再签定进口合同。失效日前签订进口合同，失效日后到货的品种，口岸药检所可接收报验。

第六条 换发《进口药品注册证》按照有关规定收费。

第七条 本规定由卫生部药政管理局负责解释。

第八条 本规定自 1991 年 7 月 1 日起执行。

Regulations on the Renewal of "Registration Certificate for Import Drug"

Article 1. On the basis of Article 10 of "Provisions Governing Import Drugs" these regulations are established.

Article 2. The renewal of "Registration Certificate for Import Drug"must be applied for voluntarily by the manufacturer or its agent, six months before the expiration of the original registration certificate.

Article 3. In the renewal of "Registration Certificate for Import Drug"an application form needs to be complete in duplicate and the following documents should be submitted:

1. Marketing and distribution certificate for the drug issued by the health authority of the drug producing country.
2. Data sheet of the drug.
3. If revision has been made on the specifications or production process of the drug after obtaining the "Registration Certificate for Import Drug", then the new one should be submitted.

All the documents mentioned above should be submitted with their Chinese translation copies.

Article 4. The following principles are observed by the Bureau of Drug Administration and Policy of the Ministry of Public Health of the People's Republic of China in dealing with the renewal of registration certificate:

1. Drugs with established efficacy, reliable quality, and be needed in clinic or pharmaceutical manufacturers of this country, their renewal shall be allowed.
2. Drugs with uncertain or disputed efficacy, clinical trial and evaluation shall be rearranged, from which to determine whether the renewal of their registration certificate be allowed.
3. Drugs can be produced domestically with a quality not inferior than foreign product and their production capacity can satisfied domestic need, the renewal of their registration certificate shall not be allowed.

Article 5. Since the date of expiration, the"Import Drug Permit"or"Registration Certificate for Import Drug"should not be used to sign contract by domestic drug importing unit. Drug arrived this country after the expiration with contract signed before the date of expiration, its application for analysis should be accepted by the Coastal Insitute.

Article 6. An evaluation fee of 1000 shall be collected for each renewal.

Article 7. The Ministry of Public Health of the People's Republic of China is responsible for the interpretation of the regulations.

Article 8. These regulations shall come into force on July 1 of 1991.

目 录

CONTENTS

进口药品品种目录
THE OFFICIAL LISTING OF IMPORT DRUGS

注册证号	Number of Certificate		X940001
药品名称及剂型	Name of Drug and Presentation	头孢克罗（氯氨苄头孢菌素）原料	KEFLOR(Cefaclor) BULK
规格	Specification		USP
产地	Country of Origin	印度	INDIA
生产药厂名称及地址	Name and Address of Manufacturer		RANBAXY LAB. LTD. INDUSTRIAL AREA - III DEWAS, MOHALL PUNJAB INDIA
申请药厂或公司名称及地址	Name and Address of Applicant		RANBAXY LAB. LTD. 10TH FL. DEVIKA TOWER 6 NEHRU PLACE NEW DELHI - 110 019 INDIA
生产国批准文号	Registration Number in Country of Origin		28/15/83
专利号	Patent Number		
发证日期	Issue Date		01/08/94
有效期限	Expiry Date		01/07/97

注册证号	Number of Certificate		X940002
药品名称及剂型	Name of Drug and Presentation	诺福丁（二氯苯胺苯乙酸）缓释颗粒	NOVOLTEN(Diclofenac) S.R.GRANULE
规格	Specification		100mg
产地	Country of Origin	法国	FRANCE
生产药厂名称及地址	Name and Address of Manufacturer	爱的发制药厂	LES LAB. ETHYPHARM 21 RUE SAINT - MATHIEU HOUDAN FRANCE
申请药厂或公司名称及地址	Name and Address of Applicant	中国苏州 十全街 51 号后门 2/304	
生产国批准文号	Registration Number in Country of Origin		2651
专利号	Patent Number		
发证日期	Issue Date		01/13/94
有效期限	Expiry Date		01/12/97

进口药品品种目录
THE OFFICIAL LISTING OF IMPORT DRUGS

注册证号	Number of Certificate		X940003
药品名称及剂型	Name of Drug and Presentation	得普乐(甲孕酮) 针剂	DEPO－PROVERA (Medroxyprogesterone) INJECTION
规格	Specification		150mg/1ml
产地	Country of Origin	比利时	BELGIUM
生产药厂名称及地址	Name and Address of Manufacturer		N. V. UPJOHN S. A. RIJKSWEG 12 2670 PUURS BELGIUM
申请药厂或公司名称及地址	Name and Address of Applicant	美商普强药厂 香港皇后大道东 37－59A 东美商业中心 710 室	UPJOHN CO. (H. K.) LTD. RM. 710 DOMINION CTR. 37－59A QUEEN'S RD. E. HONG KONG
生产国批准文号	Registration Number in Country of Origin		277S10F12
专利号	Patent Number		
发证日期	Issue Date		03/08/94
有效期限	Expiry Date		03/07/97

注册证号	Number of Certificate		X940004
药品名称及剂型	Name of Drug and Presentation	得普乐(甲孕酮) 针剂	DEPO－PROVERA (Medroxyprogesterone) INJECTION
规格	Specification		150mg/3ml
产地	Country of Origin	比利时	BELGIUM
生产药厂名称及地址	Name and Address of Manufacturer		N. V. UPJOHN S. A. RIJKSWEG 12 2670 PUURS BELGIUM
申请药厂或公司名称及地址	Name and Address of Applicant	美商普强药厂 香港皇后大道东 37－59A 东美商业中心 710 室	UPJOHN CO. (H. K.) LTD. RM. 710 DOMINION CTR. 37－59A QUEEN'S RD. E. HONG KONG
生产国批准文号	Registration Number in Country of Origin		277S10F12
专利号	Patent Number		
发证日期	Issue Date		03/08/94
有效期限	Expiry Date		03/07/97

进口药品品种目录
THE OFFICIAL LISTING OF IMPORT DRUGS

注册证号	Number of Certificate		X940005
药品名称及剂型	Name of Drug and Presentation	脱氧熊胆酸胶囊	URSOFALK (Ursodeoxycholic acid) CAPSULE
规格	Specification		250mg
产地	Country of Origin	德国	GERMARY
生产药厂名称及地址	Name and Address of Manufacturer	德国霍克大药厂	DR. FALK PHARMA GMBH LEINENWEBERSTRASSE 5 D－7800 FREIBURG GERMANY
申请药厂或公司名称及地址	Name and Address of Applicant	香港雅各臣有限公司西药核能同位素部香港湾仔骆克道 237 号	JACOBSON VAN DEN BERG (HK) LTD. 237 LOCKHART ROAD WANCHAI HONG KONG
生产国批准文号	Registration Number in Country of Origin		4177.00.00
专利号	Patent Number		
发证日期	Issue Date		04/17/94
有效期限	Expiry Date		04/16/97

注册证号	Number of Certificate		X940006
药品名称及剂型	Name of Drug and Presentation	肝活命(侧链氨基酸)粉剂	FALKAMIN ORAL POWDER
规格	Specification		26.7g
产地	Country of Origin	德国	GERMARY
生产药厂名称及地址	Name and Address of Manufacturer	德国霍克大药厂	DR. FALK PHARMA GMBH LEINENWEBERSTRASSE 5 D－7800 FREIBURG GERMANY
申请药厂或公司名称及地址	Name and Address of Applicant	香港雅各臣有限公司西药核能同位素部香港湾仔骆克道 237 号	JACOBSON VAN DEN BERG (HK) LTD. 237 LOCKHART ROAD WANCHAI HONG KONG
生产国批准文号	Registration Number in Country of Origin		
专利号	Patent Number		
发证日期	Issue Date		04/17/94
有效期限	Expiry Date		04/16/97

进口药品品种目录
THE OFFICIAL LISTING OF IMPORT DRUGS

注册证号	Number of Certificate		X940007
药品名称及剂型	Name of Drug and Presentation	优降糖 片剂	GILEMAL(Glibenclamide) TABLET
规格	Specification		5mg
产地	Country of Origin	匈牙利	HUNGARY
生产药厂名称及地址	Name and Address of Manufacturer		CHINOIN PHARMA. & CHEM. WORKS CO., LTD. H-1045 BUDAPEST TO U. 1-5 HUNGARY
申请药厂或公司名称及地址	Name and Address of Applicant	法国赛诺菲国营集团 中国分公司医药部 中国北京建外大街1号 国贸大厦2823室	SANOFI CHINA BEIJING OFFICE RM. 2823 CHINA WORLD CENTER 1 JIAN WAI STREE BEIJING 100004 CHINA
生产国批准文号	Registration Number in Country of Origin		3490
专利号	Patent Number		
发证日期	Issue Date		01/11/94
有效期限	Expiry Date		01/10/97

注册证号	Number of Certificate		X940008
药品名称及剂型	Name of Drug and Presentation	羟戊丁氨酯 针剂	NO-SPA (Drotaverine Hcl) INJECTION
规格	Specification		40mg/2ml
产地	Country of Origin	匈牙利	HUNGARY
生产药厂名称及地址	Name and Address of Manufacturer		CHINOIN PHARMA. & CHEM. WORKS CO., LTD. H-1045 BUDAPEST TO U. 1-5 HUNGARY
申请药厂或公司名称及地址	Name and Address of Applicant	法国赛诺菲国营集团 中国分公司医药部 中国北京建外大街1号 国贸大厦2823室	SANOFI CHINA BEIJING OFFICE RM. 2823 CHINA WORLD CENTER 1 JIAN WAI STREE BEIJING 100004 CHINA
生产国批准文号	Registration Number in Country of Origin		3233
专利号	Patent Number		
发证日期	Issue Date		01/11/94
有效期限	Expiry Date		01/10/97