檔　　號：
保存年限：

正本

行政院衛生署食品藥物管理局　函

機關地址：11561 台北市南港區昆陽街161-2號
傳　　真：(02)25233303
聯絡人及電話：張惠萍　(02)8590-6666#6992
電子郵件信箱：hpchang@fda.gov.tw

10478
台北市中山區建國北路二段87號10F之1

受文者：中華民國西藥代理商業同業公會 擬：會查驗登記與法規委員會刊會訊。黃聖惠 社文憲

發文日期：中華民國99年9月23日
發文字號：FDA藥字第0991412344號
速別：
密等及解密條件或保密期限：
附件：「WHO-format Certificate of Pharmaceutical Product」、「產銷證明（GMP）」、「產銷證明（非GMP）」及「外銷證明」格式各1份

主旨：為順應國際潮流及統一證明書核發格式，本局規劃以「WHO-format Certificate of Pharmaceutical Product」取代「產銷證明（GMP）」、「產銷證明（非GMP）」及「外銷證明」，倘有意見，請於文到1個月內提供本局研參，請　查照。

說明：

一、經比較「WHO-format Certificate of Pharmaceutical Product」、「產銷證明（GMP）」、「產銷證明（非GMP）」及「外銷證明」等4種證明書之刊載內容，原則上除適應症外，「WHO-format Certificate of Pharmaceutical Product」應可涵蓋其他3種證明書之刊載內容。

二、倘因應外銷國之要求，須於證明書中加刊適應症內容者，得以附件方式附於「WHO-format Certificate of Pharmaceutical Product」之後。

三、檢送案內4種證明書格式各1份供參。

中華民國西藥代理商業同業公會　收文章
99年9月27日11時23分 514 號

裝 訂 線

正本：台北市西藥代理商業同業公會、台北市西藥商業同業公會、台灣區製藥工業同業公會、中華民國西藥代理商業同業公會、中華民國製藥發展協會、中華民國開發性製藥研究協會、社團法人中華民國學名藥協會、台灣省西藥商業同業公會聯合會、高雄市西藥商業同業公會

副本：

局長 康照洲

本案依分層負責規定
授權主管科長決行

裝 訂 線

Department of Health, The Executive Yuan, Republic of China

Certificate of Pharmaceutical Product

Certificate No.
(Conforms to WHO format revised 10/1/97)

Exporting Country : Taiwan, R.O.C.
Importing Country :

1. International or National Nonproprietary Names (if applicable) and dosage forms :
1.1. Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred) :
1.2. Is this product licensed to be placed on the market for use in the exporting country?
1.3. Is this product actually on the market in the exporting country?

A	B
2A.1 Number of product-license and date of issue :	2B.1 Applicant for certificate (name and address) :
2A.2 Product-license holder :	2B.2 Status of Applicant : A=Mfr B=Packager and/or Labeler C=Neither
2A.3 Status of product-license holder : A=Mfr B=Packager and/or Labeler C=Neither	2B.3 Why is authorization lacking? not required / not requested / under consideration / refused
2A.4 Is an approved summary basis appended?	2A.3.1 or 2B.2.1 Mfr :
2A.5 Is the attached product information complete and consonant with the license?	
2A.6 Applicant for certificate if different from the license holder (name and address) :	Remarks :

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
3.1 Periodicity of routine inspection (years) :
3.2 Has the manufacture of this type of dosage form been inspected :
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?
4. Does the information submitted by the applicant satisfy the certifying on all aspects of the manufacture of the product undertaken by another party?

Address of certifying authority : Food and Drug Administration
Department of Health
The Executive Yuan, Republic of China
No. 161-2, Kunyang St, Nangang District,
Taipei City 115-61, Taiwan (R.O.C.)
Telephone : (886-2) 2653-1318

Signed by :
Director General
Food and Drug Administration
for
Minister
Department of Health
The Executive Yuan, R.O.C.

中 華 民 國 行 政 院 衛 生 署

DEPARTMENT OF HEALTH, THE EXECUTIVE YUAN

REPUBLIC OF CHINA

Date:_____ No:_____

證 明 書

Certificate

茲證明下述產品經行政院衛生署核准許可登記，准予產銷。

Department of Health, The Executive Yuan of the Republic of China hereby certifies that the product as described below is subject to its jurisdiction and is legally approved for distribution within the Republic of China.

製造廠名稱：

Manufacturer：_____(中英並排)_____

製造廠地址:

Manufacturing Plant Location：_____(中英並排)_____

藥品、含藥化妝品、醫療器材名稱：

Product Name：_____(中英並排)_____

劑型：

Dosage Form：_____(中英並排)_____

許可證字號：

Registration Number：衛署藥製字第　　號

核准日期：

Date of Issue：xx31,2002

處方、規格（型號）：

Formula、Model（Type）：

用途、效能或適應症：

Use、Intended Use（or Indication）：（中英並排）

Signed by_____

Director General
Food and Drug Administration
for
Minister
Department of Health
The Executive Yuan, R.O.C.

中 華 民 國 行 政 院 衛 生 署

DEPARTMENT OF HEALTH, THE EXECUTIVE YUAN

REPUBLIC OF CHINA

Date:_____ No:_____

證 明 書

Certificate

茲證明下述藥品經行政院衛生署核准許可登記，准予產銷。
該藥品之製造廠亦經評定已實施經濟部與行政院衛生署聯合公布推行之
優良藥品製造標準，並接受定期與不定期之稽查。
Department of Health, The Executive Yuan of the Republic of China hereby certifies that the product as described below is subject to its jurisdiction and is legally approved for distribution within the Republic of China.
It is also certified that the manufacturing establishment has been in compliance with the requirements for Good Manfacturing Practices as jointly promulgated by the Ministry of Economic Affairs and Department of Health, The Executive Yuan, R.O.C. and is subject to inspections at appropriate intervals.

製造廠名稱：
Manufacturer：_____(中英並排)_____

製造廠地址:
Manufacturing Plant Location：_____(中英並排)_____

藥品名稱：
Product Name：_____(中英並排)_____

劑型：
Dosage Form：_____(中英並排)_____

許可證字號：
Registration Number：衛署藥製字第　　號

核准日期：
Date of Issue：xx31,2002

處　方：
Formula：

適應症：
Indication(s)：(中英並排)

Signed by_____
Director General
Food and Drug Administration
for
Minister
Department of Health
The Executive Yuan, R.O.C.

中 華 民 國 行 政 院 衛 生 署

DEPARTMENT OF HEALTH, THE EXECUTIVE YUAN

REPUBLIC OF CHINA

Date:_____ No:_____

證 明 書

Certificate

茲證明下述藥品經行政院衛生署核准許可登記，准予外銷。
Department of Health, The Executive Yuan of the Republic of China hereby certifies that the product as described below is subject to its jurisdiction and is legally approved for exportation.

製造廠名稱：
Manufacturer：_____(中英並排)_____

製造廠地址:
Manufacturing
Plant Location：_____(中英並排)_____

藥品名稱：
Product Name：_____(中英並排)_____

劑型：
Dosage Form：_____(中英並排)_____

許可證字號：
Registration Number：衛署藥製字第　　號

核准日期：
Date of Issue：xx31.2002

處　方：
Formula：

適應症：
Indication(s)：（中英並排）

Signed by_____
Director General
Food and Drug Administration
for
Minister
Department of Health
The Executive Yuan, R.O.C.