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Review Article

FREE SALE CERTIFICATE (EXPORT CERTIFICATE)

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ABSTRACT

Many countries are now requiring a Certificate of Free Sale, sometimes called a "Certificate for Export" or "Certificate to Foreign Governments", as assurance from a foreign agency that the products listed on the certificate are freely sold and manufactured in the U.S. The authorized official bodies can issue a Certificate of Free Sale for products manufactured and legally sold in that of countries. A Certificate of Free Sale states that the company selling the products has submitted evidence to us that the products listed on the certificate are freely sold in the those countries.

Keywords: Certificate of export (Certificate of free sale) , USFDA , WHO , TGA , CDSCO.

INTRODUCTION

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce [1].

International trade in pharmaceutical products encompasses many thousands of products. The value of the global pharmaceutical market is estimated to exceed US$ 200 billion per year.

Some 20-30% of this amount involves international trade, while the remaining amount consists of drugs that are produced and consumed within individual countries. The dependence on imported pharmaceutical products differs between countries. In developing countries, particularly the least developed, the dependence on the importation of pharmaceutical products is much greater. In many cases it may reach 100%, as with Central African Republic, Fiji, Malawi, and Papua New Guinea, included in the present study.

The movement of pharmaceutical products in international commerce necessitates various safeguards on the part of importing countries and institutions to assure that pharmaceutical products are safe, effective, and of adequate quality when received.

The approach to quality assurance of pharmaceutical products includes a number of elements: a decision that the product is effective and safe; assurance of appropriate manufacturing conditions for its production and confirmation that these conditions fulfil requirements for Good Manufacturing Practices (GMP); and assurance of the quality of every batch through appropriate analytical testing. In the case of imported products, additional analytical testing is done to confirm that the batch received did not deteriorate in transit.[1]

WHO Certification Scheme [1]

In response to the need of developing countries to receive an assurance about the status and quality of imported products, the World Health Assembly (WHA) adopted in 1969, in resolution WHA22.50, requirements for "Good Practices in the Manufacture and Quality Control of Drugs" (GMP) (annex 1), together with the first version of the Certification

Scheme. The Scheme provided for: a) the exporting country to establish, after inspection, an up-to-date list of manufacturers complying with GMP which could be exchanged between governments; and b) the issuance of batch certificates by the responsible health authorities of the exporting country. [1]

Consultations with governments showed that neither the maintenance of lists of manufacturers, nor the issuance of batch certificates by authorities were feasible in practice.

A revised version of the Scheme entitled " WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce" was thus submitted to the WHA in 1975. The revision was adopted in resolution WHA28.65 (annex 2). The 1975 version of the Scheme is based on certification by the responsible health authorities of: a) the registration status of a particular product in the exporting country; and b) of the GMP compliance of the responsible manufacturer. The issuance of a certificate for individual batches is relegated to the manufacturer. [1]

After over a decade of experience with the scheme, it was felt that the 1975 version of the Scheme required further changes. It was revised and expanded in 1988 by the WHA in resolution WHA41.18. A modified form of the Certificate of a Pharmaceutical Product was attached to the resolution, superseding the 1975 form of this Certificate. The amendments of 1988 brought within the realm of the Scheme drug substances and finished dosage forms intended for human use, as well as a veterinary product administered to food producing animals. They also required the competent authority in the exporting country to provide copies of all approved product information and labelling as determined by the product license issued by the regulatory authority in the country of manufacture (annex 3). [1]

In 1992, the WHA, in its resolution WHA45.29, endorsed the "Guidelines for implementation of the WHO Certification Scheme". This also contained a modified form for a Certificate of a Pharmaceutical Product which superseded the 1975 Certificate of a Pharmaceutical Product.

Forms for a Statement of Licensing Status of Pharmaceutical Product(s) and for a Batch Certificate of a Pharmaceutical Product were also attached to the Guidelines (annex 4). In this resolution the WHA established a period of five years to evaluate and revise the proposed forms for the various certificates mentioned. [1]

As at December 1994, the WHO Certification Scheme has been accepted by health authorities in 138 countries, both exporting and importing pharmaceuticals, which indicates their willingness to share the responsibility for the quality of drugs moving in international commerce. [1]

The Scheme offers to importing countries information about:

a) the status of the pharmaceutical product;

b) the status of the manufacturer of the pharmaceutical product;

c) the quality of individual batches of the exported pharmaceutical product;

d) product information as approved in the country of export.

Types of Certificates[1]

The different types of certificates developed by WHO over the last two decades under the Certification Scheme, as well as examples of other certificates issued by drug regulatory authorities in the exporting countries are described below. [1]

WHO-type Certificate[1]

a) Certificate of Pharmaceutical Product (WHO 1975 type)

The 1975 version of the WHO-type Certificate of a Pharmaceutical Product is a certificate to be issued by a competent authority (regulatory authority) of the exporting country stating:

(i) that the product has been authorized to be placed on the market for use in the country including the number of permit and date of issue, or that the product has not been authorized to be placed on the market for use in the country and the reasons why;

(ii) that: a) the manufacturing plant in which the product is produced is subject to inspections at suitable intervals; and b) the manufacturer conforms to GMP requirements as recommended by WHO in respect of products to be sold or distributed within the country of origin or to be exported. [1]

b) Certificate of a Pharmaceutical Product (WHO 1988 type)

The 1988 format of the Certificate of a Pharmaceutical Product is similar to the 1975 version, but in addition the competent authority of the exporting country is required to provide copies of the complete text of all labelling and

product information which is authorized in the country of origin. [1]

c) Certificate of a Pharmaceutical Product (WHO 1992 type)

This is intended for use by the competent authority of an importing country in two situations: a) when the product in question is under consideration for a product license that will authorize its importation and sale; and b) when administrative action is required to renew, extend, vary or review such a license. The certificate provides information on the following: i) whether a product is licensed to be placed on the market, and if not, the reasons why; ii) whether the applicant manufactures the dosage forms, packages and/or labels a finished dosage form manufactured by an independent company, or is involved in none of the above; iii) if the manufacturer of the product has been inspected and the periodicity of inspection; iv) if the certificate is provisional, pending technical review; v) whether the information submitted by the applicant satisfies the certifying authority on all aspects of the manufacture of the product undertaken by another party; vi) states the names of the importing and exporting (certifying) countries. [1]

d) Statement of Licensing Status (WHO 1992 type)

This is an attestation issued by a national regulatory authority of an exporting country stating that a license has been issued for a specified product or products for use in the exporting country. It is intended for use by importing agents when considering bids made in response to an international tender and is useful only to facilitate the screening and preparation of information. [1]

e) Batch Certificate (WHO-type)

A certificate issued by either the manufacturer or by the competent authority of an exporting country confirming that the quality of a specific batch of the product conforms to specifications approved at the time of issuance of product license by the competent authority in the exporting country. The batch certificate indicates the name, dosage form, batch number, expiry date, storage condition of the product as well as a reference to the Certificate of a Pharmaceutical Product. [1]

Other Certificates (non WHO-type) [1]

a) Free Sale Certificate: A certificate issued by a national regulatory authority of an exporting country based on national legislation confirming that the product is freely sold in the country but without any indication that the product is evaluated for safety and efficacy and is registered for use in the country.

b) GMP Certificate

A certificate issued by a national regulatory authority of an exporting country confirming that the manufacturer complies with GMP requirements.

c) Analytical Batch Certificate

A certificate issued by a manufacturer confirming that the quality of a specific batch corresponds to the specifications for the product at the time when the batch was released. It contains results of analytical tests but does not mention the relevant Certificate of a Pharmaceutical Product issued by the regulatory authority of the exporting country as recommended by WHO. [1]

Summery analysis by WHO [1]

As per WHO , the study showed that there is an extensive use by most countries of Free Sale certificates.

Analysis of data collected from the survey of 15 importing countries clearly shows that only two countries used the WHO Certification Scheme in drug registration in the format recommended by WHO. Eight countries requested national certificates, while the remaining five countries did not request any certificate since they do not have a system of drug registration.

Procurement data collected also revealed that, with the exception of one country, the rest requested different types of certificates during procurement. The certificates requested and their percentages were: WHO type certificates 27%; Certificate of Analysis 20%; Free Sale and Batch Certificate 27%; Free Sale Certificate 6%; GMP Certificate and Certificate of Quality Control 6%; and Registration Certificate 6%.[1]

FDA Certification [2]

An export certificate is a document prepared by FDA containing information about a product's regulatory or marketing status.

This guidance document is intended to provide a general description of FDA Export Certificates to industry and foreign governments. Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the

Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§321-397, and other statutes FDA administer. [2]

FDA Export Certificates [2]

Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a "certificate" for products regulated by the Food and Drug Administration (FDA). A certificate is a document prepared by FDA containing information about a product's regulatory or marketing status. [2]

Foreign governments want FDA Export Certificates [2]

In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States or meet specific U.S. regulations, for example current Good Manufacturing Practice (cGMP) regulations. Review of an FDA Export Certificate may be a required part of the process to register or import a product into another country [2].

Types of Export Certificates issued by FDA [2]

At the current time, FDA issues the following types of Export Certificates, although not all certificate types are issued for every FDA regulated product:

•□□The "Certificate to Foreign Government" is for the export of products that can be legally marketed in the United States.

•□□The "Certificate of Exportability" is for the export of products that cannot be legally marketed in the United States, but meet the requirements of sections 801(e) or 802 of the Act and may be legally exported.

•□□The "Certificate of a Pharmaceutical Product" conforms to the format established by the World Health Organization (WHO) and is intended for use by the importing country when considering whether to license the product in question for sale in that country.

•□□The "Non-clinical Research Use Only Certificate" is for the export of a product, material, or component, for non-clinical research use only, that is not intended for human use and which may be marketed in, and legally exported from the United States under the Act. These non-clinical research use only materials will be labeled in accordance with 21 CFR 809.10(c)(2) or 21 CFR 312.160, as appropriate, and exported as they are presently being sold or offered for sale in the United States.

•□□The "Certificate of Free Sale" (Certificates for Export) is for food and cosmetic products and dietary supplements that may be legally marketed in the United States.

•□□The "Health Certificates for Food/Feed" currently required primarily by the European Union (EU), are usually consignment-specific and often contain language pertaining to "compliance" of the particular product/consignment with foreign regulations. As a matter of policy, FDA does not issue export certificates that attest to compliance with another country's requirements. Rather, FDA may work with other governments to develop mutually acceptable language for the certificate, e.g., language recognizing "equivalence" rather than "compliance".

•□□The "Specified Risk Materials of Bovine, Ovine and Caprine Origin Certificate" is used for the export of gelatin that can be legally marketed in the United States. These certificates address concerns on raw material in regard to transmissible spongiform encephalopathies. [2]

FDA required to issue Export Certificates [2]

Section 801(e)(4) of the Act provides that FDA shall, upon request, issue certificates for human drugs and biologics, animal drugs, and devices that meet certain requirements of the Act. FDA is not required by law to issue certificates for foods, animal feeds, food and feed additives, cosmetics and dietary supplements that can be marketed, sold, and distributed in the United States, but the agency intends to continue to provide this service as resources permit[2].

In case of unapproved products[2]

The 1996 FDA Export Reform amendments to the Act provided for FDA to issue certificates for exports of certain products even though the products are not allowed to be marketed in the United States. FDA issues Certificates of Exportability for biologics, animal drugs, and devices that may be exported under these provisions of the Act but may not otherwise be marketed, sold, offered for sale, or distributed in the United States. For human drug products, FDA issues a Certificate of a Pharmaceutical Product containing a special notation that the product is unapproved instead of a Certificate of Exportability. FDA does not issue Certificates of Exportability for foods, dietary supplements, and cosmetics. [2]

FDA mean, when it attests to compliance with current Good Manufacturing Practice (cGMP) regulations in an Export Certificate[2]

FDA performs periodic inspections for compliance with cGMP regulations for drugs, biologics, and medical devices of United States manufacturers that are registered and listed with us. FDA bases its attestation of compliance with cGMP regulations on the manufacturer's most recent FDA inspection or other available information. Generally, FDA cGMP regulations are intended to assure that the manufacturer can manufacture, process, package, and hold a product to assure that it meets the requirements of the Act as to safety, identity, strength, quality, and purity. [2]

Conditions under which FDA refuse to issue an Export Certificate[2]

FDA will not issue a Certificate to Foreign Government or a Certificate of a Pharmaceutical Product for products that do not meet the applicable requirements of the Act. Additionally, such certificates will not be issued if FDA has initiated an enforcement action (e.g., a seizure or an injunction). Other examples of circumstances for which certificates will not be issued include:

•□□Failure of the manufacturing facility(ies) to operate in compliance with the cGMP regulations (unless the particular exported product is not affected by the specific cGMP deficiencies);

•□□Manufacturing facility(ies) not registered or listed with FDA; and

•□□Manufacturing facility(ies) for which FDA has no inspectional information.

FDA will not issue Certificates of Exportability for products subject to section 802 of the Act if the manufacturing facility(ies) does not comply with cGMP regulations, unless the particular exported product is not affected by the specific cGMP deficiencies.

FDA also will not issue Certificates of Free Sale and Health Certificates for Food/Feed (which are used for food and cosmetics) when products are removed from sale or not eligible for legal sale in the United States (e.g., the product is under seizure or the firm is under injunction)[2].

FDA charges a fee for Export Certificates[2]

For human drug, biolo gic, animal drug, and device export certificates issued under section 801(e)(4) of the Act, the agency may charge a fee of up to $175 if FDA issues a certificate within 20 days of receipt of a request for such a certificate. This fee may vary depending on the product type, but it will not exceed $175. [2]

The legal requirements for exporting unapproved products under sections 801(e) and 802 of the Act[2]

Sections 801(e) and 802 of the Act contains numerous legal requirements for exporting unapproved products and other products that do not comply with the relevant requirements of the Act for distribution and sale in the United States. For sections 801(e) and 802 of the Act refer to the following internet address: http://www.fda.gov/ora import/impexp/ ora_impexp_sec.html.

For further information on draft guidance announced for public comment and FDA regulations concerning the export of products that cannot be distributed or sold in the United States, refer to the following documents:

•□□February 1998, Draft FDA Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996. Refer to the following internet address:

http://www.fda.gov/opacom/fedregister/frexport.html.

•□□December 19, 2001 (66 FR 65429), Final Rule: Exports: Notification and Recordkeeping Requirements to be codified at 21 CFR 1.101. [2]

FDA's cGMP requirements for drugs, devices and biologics [2]

FDA's cGMP requirements for drugs are the requirements for the methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug (including a biologic) to assure that such drug meets the requirements of the Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess (21 CFR Parts 210 and 211). The cGMP requirements for devices are set forth in the quality system regulation (21 CFR Part 820). The requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. Biological products, depending on their intended use, must meet the cGMP requirements for either drugs or devices. [2]

CERTIFICATE OF FREE SALE REQUIREMENTS [3]

FDA can issue a Certificate of Free Sale for products manufactured in the U.S. if the following requirements are met:

• For products that are manufactured in the U.S. you must be able to prove this by submitting a written declaration from the manufacturer (a signed declaration from your company if you are the manufacturer) stating that the products are manufactured in the United States.

• For each product you would like listed on the Certificate of Free Sale, your company must submit copies of invoices showing the sale of each product to two (2) different U.S. customers. The invoices should be dated within the last 12 months and the product names must be the same as how they will appear on the Certificate. Please note that if you have more than one product, we can list multiple products on one Certificate (though we will still need copies of invoices showing the sale of each product to two different U.S. customers).

• Please specify for which country/countries you would like the Certificate(s) issued.

• Please specify exactly how the products should be listed on the Certificate(s) (this should coincide with how they are listed on the commercial invoice). We will also need to know exactly how you want your company name and address to read.

• If the FDA covers the product, we cannot issue a Certificate of Free Sale for you. You must contact the FDA directly and have them issue the certificate. [3]

Fees

Fees are per individual Certificate per country. [3]

UK GUIDELINES [4]

UK traders, when exporting consumer products to certain markets, are required to provide certification that those products may be lawfully sold in the United Kingdom. To help exporters meet this requirement the Department for Business, Innovation & Skills (BIS) can provide a Certificate of Free Sale (CFS) provided the product is not regulated by another government department. They are issued free of charge to bona fide UK exporters on application to the address given at that end of this guidance.

A CFS will normally only be issued by BIS for cosmetics, toiletries, detergents, approved disinfectants, domestic cleaners, industrial chemicals, chemical raw materials or food handling materials. They may also be issued for other chemical based products provided they do not fall to the responsibility of another government department. Other government departments that issue CFS or equivalent documents are Department of the Environment, Food and Rural Affairs (DEFRA), the Department of Health (DH) and the Health and Safety Executive (HSE). [4]

AUSTRALIAN REGULATORY GUIDELINES (THERAPEUTICS GOODS ADMINISTRATION-TGA)[5]

Sponsors wanting to export medical devices from Australia must meet certain regulatory requirements set out in the Therapeutic Goods Act 1989 (the Act) and the Therapeutic Goods (Medical Devices) Regulations 2002. [5]

Certificates of Free Sale [5]

A Certificate of Free Sale is issued by the TGA for included medical devices or medical devices exempt under item 1.2, Part 1, Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002 in situations where the TGA has not issued or reviewed the manufacturer's Conformity

Assessment Certification

A Certificate of Free Sale also remains valid as long as the devices covered by the certificate remain unchanged and current on the ARTG or the exemption under Schedule 4 remains unchanged. [5]

Application for free sale certificate (Export certificate)[5]

(1) The Secretary may issue export certification for goods for therapeutic use in humans, including certifications for the purposes of the World Health Organisation Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

(2) A State or Territory must not issue export certifications for goods for therapeutic use in humans.

(3) Such fee as is prescribed is payable in respect of :

(a) an application for a certification under this section; and

(b) where an inspection of manufacturing premises is necessary for the purposes of the issue of a certification under this section—the inspection of those premises.

INDIAN REGULATORY GUIDELINES (Central Drugs Standard Control Organization Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India - CDSCO) [6]

In India import, manufacturing, sale and distribution of drug is regulated under Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945 (hereinafter refer as Act) made there under. At present, bulk drug (Active Pharmaceutical Ingredients) and finished formulations are regulated under the said Act. Any substance falling within the definition of drug (Section 3b of the Act) required to be registered before import into the country. Not only drug but the manufacturing site needs to be registered for import. If the drugs, fall within the definition of New Drug (Rule 122 E of the Act), the new drug approval is the pre-requisite for submission of application for Registration and or import of drug. The application for Registration and import can be made to the Licensing Authority under the Act i.e. to the Drugs Controller General (I) at CDSCO, FDA Bhawan, Kotla Road, Near Bal Bhawan, New Delhi by the Local Authorized Agent of the foreign manufacturer having either manufacturing or sale License or by the foreign manufacturers having a whole sale License in the country. [6]

Central Drugs Standard Control Organization
Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India

1.4	**A brief profile of the manufacturer's research activity**
A	Name of the drug / drug product which are original research product of manufacturer
B	A brief profile of the manufacturer's business activity in domestic as well as global market.
C	Letter of Power of Attorney
D	Letter for Authorized signatory
E	a) A copy of plant registration / approval certificate/ Establishment License issued by the Ministry of Health / National Regulatory Authority of the country of origin. (Notarized Copy)
F	b) A copy of approval, if any, showing the drug is permitted for manufacturing and/or marketing in the country of origin.
G	c) A copy Certificate of Pharmaceutical Product (CPP) as per WHO GMP certification scheme for imported drug products OR Certificate of Good Manufacturing Practices (cGMP) & Free Sale Certificate (FSC) from country of origin for imported Drug Products (Duly Notarized Copy)
H	A copy of market authorization/ permission to manufacture in the country of origin the Bulk Drug/ Drug Product meant for import to India
I	Domestic price of the Drug / Drug product to be registered in India in the currency in the country of origin
J	Registration/ Market authorization of Drug/ Drug Product worldwide along with Registration Certificate(Market Authorization) it should include list of country where import permission or marketing authorization has been granted/ pending or cancelled or withdrawn with date
K	List of countries where drug/ drug product is patented
L	Copy of Plant Master File (Duly Notarized)
1.4.1	Information about the experts
1.4.2	Quality
1.4.3	Non-Clinical
1.4.4	Clinical
1.5	Environmental risk assessment: (if applicable)
1.6	Information regarding Pharmacovigilance
1.7	Information relating to Clinical Trials
1.8	Samples from three consecutive batches, quantity sufficient for three analysis
1.9	Undertaking by the manufacturer

Figure 1: Various modules and contents for guidance document (Import and registration division) [6]

HOW TO OBTAIN THE CERTIFICATE OF FREE SALE OR EXPORT CERTIFICATES ? [7]

Anyone who exports a drug may submit a complete application for export certification. Certification is intended for a drug which meets the requirements of 801(e)(1) of the Food Drug and Cosmetic Act [21 U.S.C. 381(e)(1)] or meets the applicable requirements of the Act .

Process to apply for a Certificate of free sale[7]

- Submit Form 3613b
- FDA currently allows exporters to submit the CPP application in a letter format
- FDA will be transitioning to accept CPP application solely using Form 3613b

Required Application Information [7]

- Authorization to Release Information
- Billing contact
- Certification Statement
- Name of Applicant
- Applicant Contact Information
- Country of Destination
- Federal Tax Identification Number (TIN)
- FDA Marketing Authority
- Marketing Status in the Exporting Country (U.S.)
- Status of Applicant
- Complete Manufacturing Facility Address
- Facility Registration Number
- Number of certificates requested
- U.S. Trade name (the drug product's brand name)
- Bulk Substance Generic Name

Additional Required Information[7]

Approved Drug Products

- NDA, ANDA, or AADA Approval Letter
- Container Label(s)
- Package Container (Immediate)
- Package Insert
- Status of Product-license Holder

Over-the-Counter (OTC) Drug Products

- Title of the applicable monograph
- Product Label(s)
- Immediate Package Container Label

Unapproved Drug Products

- Product Identification Statement
- Product composition

Active Pharmaceutical Ingredients (API)

- Original sample of the current bulk container label

For Export Only

- Formulation page

Foreign Manufactured Drug

- Certification of Exportation from the U.S. for Foreign Manufacturing Sites

Attachment[7]

- An application for one country requires two sets of attachments

(a) set to attach to the certificate package

(b) set for FDA files

- Attachments not to exceed five pages per CPP
- Consulting importing country to determine what type of information is required on CPP

FOR UK COUNTRIES[8]

Applications for a CFS must be made in writing

a. The letter requesting the certificate must include the following information:-

i. The name of the country for which the CFS is required.

ii. Confirmation that the products are on free sale in the UK or if the products are for export only, that they may be freely sold in the UK.

iii. A declaration must be made that the products meet all statutory requirements and specify the legislation. For example if the products are toiletries or cosmetics then the relevant legislation is the Cosmetic Products Enforcement Regulations 2013.

If the products are food contact materials then the relevant legislation may be the Materials and Articles in Contact with Food EC Regulation No. 1935/2004, The Ceramic Ware (Safety) Regulations 1988 or whatever is appropriate.

If the products are approved disinfectants a declaration must be made that they meet all statutory requirements in the UK and need not be registered with DEFRA.

If the products fall within the EU Biocides Regulation 258/2012 (EU BPR) the following information must also be listed. Product name, name(s) of the active ingredient(s), CAS number(s) of the active ingredient(s) and the product type number(s) that apply to the product.

iv. If the application relates to raw materials the end use or final product should be specified wherever possible.

v. A statement certifying that the contents are true and correct should be included in the letter. BIS does not check that the products comply with any statutory obligation. The information given in such documents is entirely the responsibility of the applicant company.

b. Every application must include a schedule for attachment to each CFS required. Although more than one product may be included on the schedule you will need to include a schedule for each country of export. The schedule MUST include the product name and description, and the name and address of the manufacturer of the product(s). If only the name of the supplier is shown on the schedule then BIS must still be informed of the name of the manufacturer(s). This information must be included in the letter requesting the certificate, it will be treated as commercial in confidence and will not form part of the CFS. Schedules must be typed and three templates of the standard format are attached. You must complete the one which is relevant to your company. If you are the manufacturer then the first template is the relevant one. A supplier would use the second or third template. Please note that additional information/statements must not be included on the schedule.

3. In the case of Nigeria a combined Certificate of Manufacture and Free Sale may be required in addition to the CFS. Please contact this office for further details.

4. The Department for Business, Innovation & Skills also issues Certificates of Manufacture for the purpose of registration and licensing of pesticides in certain markets. Please refer to the Certificate of Manufacture Guidance Notes.

5. Postal requests - it would be helpful if traders could send a pre-addressed envelope or label. The CFS will be posted out by first class post unless the applicant makes alternative arrangements. [8]

AUSTRALIAN REGULATORY GUIDELINES (THERAPEUTICS GOODS ADMINISTRATION-TGA)[9]

Following steps are required to obtain the free sale certificate by TGA. [9]

Process for including export only devices on the ARTG

The following flowchart summarises the process for including an export only medical device on the ARTG via the TGA eBusiness Services (eBS):

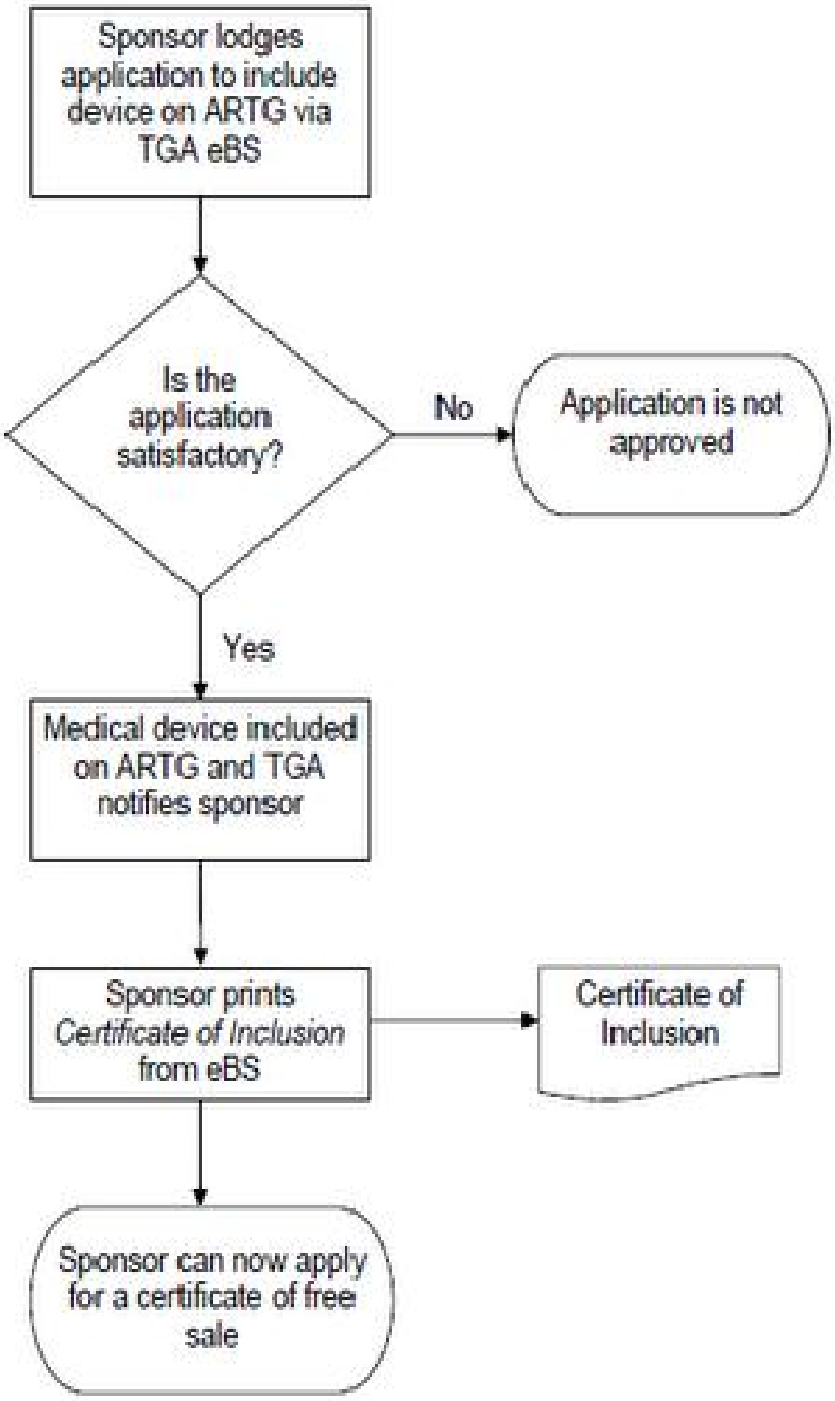

Figure 2: Process for export drugs and medical devices by ARTG [9]

LAYOUT

FREE SALE CERTIFICATE OF INDIA[10]

Appendix 39

APPLICATION FOR FREE SALE & COMMERCE CERTIFICATE

1. Name of the firm / Company :
2. Address of Registered Office :
(I) Tel No :
(II) Fax No :
(III) e.mail ID
3. Importer Exporter Code No :
(I) Code No.
(II) Name & Address of issuing authority

4. Registration –cum-Membership Certificate (RCMC) details
(I) Name of the Council
(II) Registration No and date
(III) Validity
5. Brief Description of exports :
(I) Details of foreign buyer with complete address, e.mail ID etc.
(II) Brief description of items to be exported under the certificate
6. Whether the items of export fall under the Drugs & Cosmetics Act. 1940 . If so, indicate the same. :

7. Details of items for which Free Sale & Commerce Certificate is sought to be obtained (Annexure A to be attached duly self-certified)

8. I hereby declare that items listed in Annexure A,
(I) are not prohibited or restricted for export under Schedule 2 of ITC (HS) and are free for export;
(II) all the items listed in Annexure A have usage in hospitals, nursing homes and clinics, for medical and surgical purposes;
(III) all the items listed above are not covered under Drugs & Cosmetics Act, 1940.

(Signature)
Name & Designation of the Authorized Signatory
Seal of the Company

DECLARATION / UNDERTAKING

1. I / We hereby declare that the particulars and the statements made in this application are true and correct to the best of my / our knowledge and belief and nothing has been concealed or held there from.
2. I / We fully understand that any information furnished in the application if found incorrect or false will render me / us liable for any penal action or other consequences as may be prescribed in law or otherwise warranted.
3. I / We undertake to abide by the provisions of the FT (D & R) Act, 1992, the Rules and Orders framed there under, FTP, HBP v 1 and HBP v2 and ITC (HS).
4. a. I / We hereby certify that the firm / company for whom the application has been made has not been penalized under Customs Act, Excise Act, FT (D & R) Act 1992 and FERA / FEMA.
   b. I / We hereby certify that none of the Proprietor / Partner(s) / Director(s) / Karta / Trustee of firm / company, as the case may be, is / are a Proprietor / Partner(s) / Director(s) / Karta / Trustee in any other firm / Company which has come to adverse notice of DGFT.
   c. I / We hereby certify that the Proprietor / Partner(s) / Director(s) / Karta / Trustee, as the case may be, of the firm/company is / are not associated as Proprietor / Partner(s) / Director(s) / Karta / Trustee in any other firm / company which is in the caution list of RBI.
   d. I / We hereby certify that neither the Registered Office / Head Office of the firm/company nor any of its Branch Office(s) / Unit(s) / Division(s) has been declared a defaulter and has otherwise been made ineligible for undertaking import / export under any of the provisions of the Policy.
5. I / We hereby declare that I / We have not obtained nor applied for such benefits (including issuance of an Importer Exporter Code Number) in the name of our Registered / Head Office or any of our Branch(s) / Unit(s) / Division(s), to any other Regional Authority.
6. I / We hereby declare that I/we have perused the list of SCOMET items as contained in the Appendix 3 to the Schedule 2 of the ITC (HS) and that the item(s) exported / proposed to be exported does not fall within this list and that I / We agree to abide by the provisions of FTP for export of SCOMET items contained in the FTP, Schedule 2 of ITC (HS) and the HBP v1, irrespective of the scheme under which the item is exported / proposed to be exported.
7. I / We solemnly declare that I / We have applied for / obtained a RCMC to the EPC which pertains to our main line of business. In case we have applied to any other council, the application has been made within the purview of the provisions of Para 2.67 and Para 2.67.1 of the HBP v1.
8. I hereby certify that I am authorized to verify and sign this declaration as per Paragraph 9.9 of the Policy.

Place
Date

Signature of the Applicant
Name
Designation
Official Address
Telephone
Residential Address
Email Address

FREE SALE CERTIFICATE OF USA[11]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

CERTIFICATE OF FREE SALE

1. Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that the copy attached (see attached list) is a true copy of material on file in the Food and Drug Administration, Department of Health and Human Services and is a part of the official records of said Administration and Department.

Letter Dated:

August 28, 2014

To Whom it May Concern

from, Constance Hardy

regarding

JETRYTE CITRUS (3 TABLETS)

2. In witness whereof, I have pursuant to the provisions of Title 42, United States Code, Section 3505, and 1410.20 of the FDA Staff Manual Guide, hereto set my hand and cause the seal of the Department of Health and Human Services to be affixed this 28th day of August, 2014.

Charlotte A. Christin

Charlotte A. Christin
Acting Director, Division of Dietary and Supplement Programs
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition

By direction of the Secretary of Health and Human Services

This Certificate expires on August 28, 2016.

FREE SALE CERTIFICATE OF MASSACHUSETTTES[12]

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Food Protection Program
305 South Street, Jamaica Plain, MA 02130-3597
617-983-6712 617-983-6770 - Fax

Food Export/Certificate of Free Sale Application

1. **Food Manufacturer's Information**:

Manufacturer's Name _____ State License/Registration Number _____

Doing Business As Name (if other than above, and you wish this name to appear on the export certificate) _____ Contact Person's Name _____

Street Address _____ Contact's Phone and Fax Numbers _____

City _____ State _____ Zip _____ Country _____ Contact's Email Address _____

2. **Exporting Company's Information**: (if applicable)

Exporting Company's Name _____ State License/Registration Number _____

Street Address _____

City _____ State _____ Zip _____ Country _____ Contact Person _____

Contact's Phone and Fax Numbers _____ Contact's Email Address _____

3. **Notarization Required?** **Yes** **No**

4. **Product Description**: _____
Continue on additional page(s) as needed.

5. **Send Certificate to**: **Manufacturer** **Exporter**

6. **Send Certificate via**: _____ _____
Carrier Name (US Mail/UPS/FEDEX) Account Number/Expiration Date

7. **Fees**: Quantity of Certificates Requested _____ x $ 75.00 = $ _____ (Total)

Attach a Check made payable to the Commonwealth of Massachusetts and mail to the above address

8. **Signature**: The undersigned verifies that all ingredients are approved for use by the USFDA or appear on the GRAS list, and each product is intended for human consumption and available for sale in the U.S. without restriction. I hereby certify that the above information is true to the best of my knowledge and that I will comply with all applicable laws and regulations of the Commonwealth of Massachusetts and the Department of Public Health pertaining to the activity for which I am applying. In addition, pursuant to M.G.L. c. 62C, § 49A, I certify under the penalties of perjury that to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

Signature _____ Title _____ Date _____ Tax or Federal ID# _____

ELEMENTS [1]

Looking at the administrative side, quality assurance of an imported product would ideally include the following elements:

a) Registration of the product in the country of manufacture;

b) Approval of manufacturing conditions by pharmaceutical inspection of the manufacturing plant;

c) Quality analysis of a batch of the product by the manufacturer's laboratory before the product is released;

d) Licensing of the product in the country of importation;

e) Quality analysis of a sample of the product taken from every batch after receipt of goods at the country of destination.

Such an ideal situation is only rarely met in practice as it would require the existence and proper operation of regulatory authorities in both the exporting and importing countries and a considerable expenditure of resources. In most developing countries, the necessary resources are non-existent. The approaches used in practice by the majority of importing countries are, therefore, aimed at obtaining at least a partial assurance that imported products are licensed and approved for use in the country of origin, and are of acceptable quality.

EXAMPLES OF FREE SALE CERTIFICATE[12,13,14,15]

JEREMIAH W. (JAY) NIXON

DEPARTMENT of AGRICULTURE
STATE OF MISSOURI
JEFFERSON CITY

Serving, promoting and protecting the agricultural producers, processors and consumers of Missouri's food, fuel and fiber products.

DR. JON HAGLER

Date

CERTIFICATE of FREE SALE

TO WHOM IT MAY CONCERN:

The undersigned, of the Missouri Department of Agriculture, State of Missouri, United States of America, certifies that **(company name)** headquartered in **(city and state – USA)** with a manufacturing facility located at **(location – city and state – USA),** is a firm known to us.

Their manufactured product(s), **(product name), (brief description of product)**, is/are available for free sale in the State of Missouri and distributed generally throughout the United States. To the best of my knowledge, there is no prohibition against export of this/these product(s) into the country of **(name of country).**

As a matter of policy, the Missouri Department of Agriculture, while assisting and promoting sales, does not endorse any particular products.

_____
Name
International Marketing Specialist
Ag Business Development Division

Subscribed and sworn before me this ____ day of _____, **20__.**

_____
Notary Public – State of Missouri

Division of Agriculture Business Development
GEORGE WASHINGTON CARVER STATE OFFICE BUILDING
Ph. (573) 751-4762 • 1616 Missouri Boulevard • P.O. Box 630 • Jefferson City, MO 65102-0630 • FAX (573) 751-2868 • www.mda.mo.gov

Food and Drug Administration

Ministry of Public Health, Thailand

CERTIFICATE OF FREE SALE

Ref. No. 1-5-03-99-10-00326 15 February 2010

It is hereby certified that the cosmetic product(s), listed herein, in compliance with the Cosmetic Act B.E. 2535 (1992 A.D.) of Thailand,manufactured by

SABOO (THAILAND) CO.,LTD,
39/108 OSATIS 1 VILLAGE, CHOCKCHAI 4 SOI 31/1 ,
LAD PRAW 53, LAD PRAW ROAD, BANGKOK, 10230 THAILAND,

may/can be freely sold in Thailand.

Product Listing : 104 Item(s)

1. SABOO NATURAL SOAP - AMERICANO COFFEE
2. SABOO NATURAL SOAP - APPLE
3. SABOO NATURAL SOAP - APRICOT

VALID UNTIL : 14 February 2012

(Pochanee Sinsomboon)
Pharmacist Cosmetic Control Division For Secretary-General
Food and Drug Administration

ท้ายหนังสือนี้ หรือ Ref. No. แสดงบนฉลากหรือประกาศโฆษณา
Cosmetic Control Group, Bureau of Cosmetic and Hazardous Substances Control
Food and Drug Administration, Ministry of Public Health 88/24 Tiwanon Road, Nonthaburi 11000, Thailand
Tel. : 66 2590 7244 , Fax. : 66 2591 8468

AFFIDAVIT FOR CERTIFICATE OF FREE SALE

Date: _____

To Whom It May Concern:

This document hereby releases the Miami Beach Chamber of Commerce from any and all liability with regard to issuing this Certificate of Free Sale.

The Miami Beach Chamber of Commerce, a recognized Chamber of Commerce under the laws of Florida, United States, states that, based solely on the exporter's declaration, the Chamber believes that the goods described are products which are manufactured and sold in the United States of America and exported to Countries of Destination. The Chamber assumes no responsibility and makes no warranty, expressed or implied, concerning the goods, or any documents relating thereto, and assumed no responsibility for the truth or accuracy of any statements or any of the documents mentioned therein.

Name: _____

Signee: _____

Company: _____

Date: _____

Notary Stamp:

Date:

CERTIFICATE OF FREE SALE

We, the Food Safety Program, Food Safety and Consumer Services Division, Washington State Department of Agriculture, the agency responsible for enforcement of the Washington Food, Drugs and Cosmetics Act, Chapter 69.04 RCW and the Washington Food Processing Act Chapter 69.07 RCW hereby certify:

That the products manufactured/exported by

WSDA LICENSED FOOD PROCESSOR
ADDRESS
CITY, STATE ZIP

- have been prepared in a plant which is licensed, inspected by, and has been approved by this department;
- that to the best of our knowledge the products contain no harmful constituents and are fit for human consumption.
- We certify that the goods are freely sold in the United States of America.
- This certificate is not intended to endorse the effectiveness or support any medical or health claims concerning these products, only that they were manufactured in a facility that is under license and under sanitary inspection by this department.

-Description of the product and additional information given by the manufacturer/exporter:
-This facility has been inspected and meets the Food Safety requirements of the State of Washington, as well as the Title 21 Code of Federal Regulations (CFR) Part 110- Current Manufacturing Practices in Manufacturing, Packing and Holding Human Food (cGMP).-

PRODUCT: DESCRIPTION OF PRODUCT(S)

Sincerely,

FOOD SAFETY AND CONSUMER SERVICES DIVISION

_____
Signature of Responsible Official
Customer Service Specialist 2
Food Safety Program
Washington State Department of Agriculture

State of Washington
Thurston County

Sworn and subscribed to before me this _____day of _____2013.

_____
Notary Name
Notary Public
Residing in: Olympia, Washington
My Commission Expires: 10/29/2015

The Scheme is an administrative instrument that requires a participating Member State (a certifying country), upon application by a commercially interested party (the applicant company), to certify/attest to the competent authority of another participating Member State (the recipient country) that:

☐ A specific pharmaceutical product is authorized for marketing in the certifying country, or if not, the reason why authorization has not been accorded;

☐ The manufacturing facilities and operations conform to good manufacturing practices (GMP) as recommended by FDA and WHO.

The Scheme operates as follows:

1. The certificate recipient authority has in its national medicine legislation or guidelines a requirement for the submission of a Certificate for a Pharmaceutical Product (CPP) for products being imported into the country as a support to ensure the quality of the product being imported. (In some countries the CPP forms part of the dossiers to be submitted to the national medicine regulatory authority (NMRA) to have a product registered by the authority).

2. The applicant/importing company requests a CPP from the certifying authority through the exporting company.

3. The certifying authority issues a CPP to the importing/applicant company via the exporting company. (At the time of the development of the Scheme the understanding was that a CPP would be sent directly to the recipient authority by the issuing authority. The practice of receiving Free sale certificate at present is as shown in the diagram.)

Pharmaceutical products covered under the Scheme are:

☐ FPPs intended for administration to human beings;

☐ Pharmaceutical products intended for administration to food-producing animals;

☐ Active pharmaceutical ingredients (APIs).

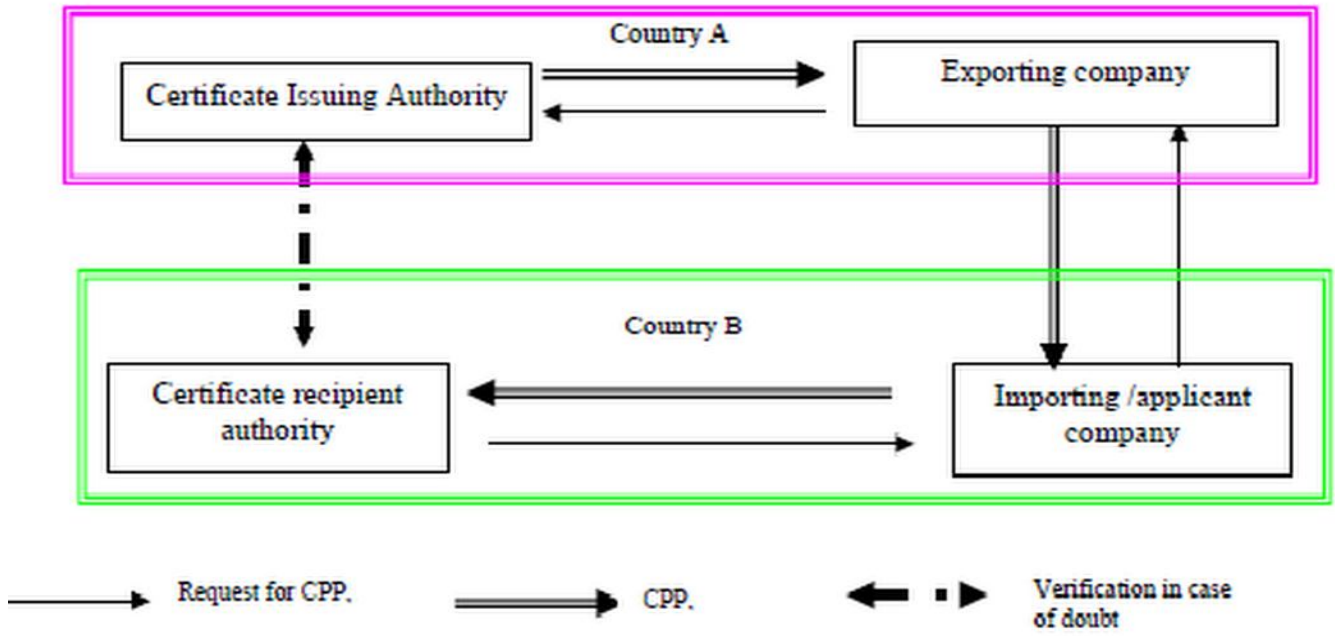

Figure 3: Application Process of Free sale certificate

REFERENCES

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2. http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm, assessed on 22/12/2014.
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5. https://www.tga.gov.au/form/application-certificate-free-sale-or-export-certificate-medical-device, assessed on 12/12/2014.
6. http://www.cdsco.nic.in/writereaddata/Guidance%20documents.pdf , assessed on 18/12/2014.
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9. https://www.adia.org.au/uploads/library/tga-devicesregulatoryguidelines.pdf, assessed on 21/12/2014
10. http://dgft.delhi.nic.in/dgftcla/RTI_PDF/delpower.pdf, assessed on 22/12/2014
11. www.fda.gov/Food/GuidanceRegulation/.../Exporting/ucm2006911.htm, assessed on 22/12/2014
12. http://www.mass.gov/eohhs/docs/dph/environmental/foodsafety/certificate-free-sale-instruction.pdf, assessed on 22/12/2014
13. http://agriculture.mo.gov/abd/intmkt/pdf/certoffreesalesample.pdf, accessed on 16/12/2014
14. www.agr.wa.gov/FoodAnimal/FoodProcessors/docs/certoffree.pdf, , accessed on 16/12/2014
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