Export Certificates for Medical Devices

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Outline

- Purpose and background
- Use of export certificates
- How to choose a certificate type
- Types (including Export permit)
- How to request
- Processing
- Record keeping

Purpose of Presentation

- The purpose of the presentation is to review the export certification process for medical devices, describe what “certificates” are, and the types of export certificates that a manufacturer/ distributor may request.

Background

- Manufacturers of medical devices are often asked by foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic (FD&C) Act (and other acts the Food and Drug Administration (FDA) administers).
- Under the FDA Export Reform and Enhancement Act of 1996 (the Act), the FDA is authorized to issue certificates for devices.

Background

- Certificates are a self certification process. Requestors sign an exporter's certification statement.
- Any medical device that is legally marketed in the U.S. may be exported anywhere in the world without prior FDA notification or approval.

Export Reform and Enhancement Act of 1996

The law allows:

- Manufacturers to request a certificate for medical devices they are exporting
- FDA to issue or refuse the export certificates, and
- FDA to charge a fee for issuing export certificates.

Use of Export Certificates

Foreign governments often seek official assurance that products exported to their countries under the certificate meet specific criteria. FDA issues certificates, that depending on the certificate type, may certify that:

- The devices listed can be legally marketed in the U.S.
- Are compliant with the FD&C Act
- Meet Good Manufacturing Practices (cGMPs)

Use of Export Certificates

- Export certificates requests are ONLY for devices that are being physically exported from the U.S.
- Export certificates can ONLY be requested by a United States based firm
- Export certificates are solely for export purposes and may not be used for domestic advertising
- CDRH will only issues certificates for medical devices. It will not issue any certificate that contains medical products that are considered drugs or biologics

Export Certificates

- Export certificates are printed on special security paper with built in features to discourage tampering or counterfeiting.
- Each certificate is good for 2 years from the date it is notarized
- Sample certificate

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Certificate No. 122-10-2008

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	Name of Manufacturer/Distributor, Address
Hip Hop Knee Implant System See Attached List (Two Pages)	Dave's Medical Devices 2094 Gaither Road Rockville, MD 20850 USA

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Theresa McDonald
Chief, Regulatory Policy and Systems Branch
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this ___ day of ___ ___ month 2008 year.

Choosing a Certificate Type

To determine which type of certificate to request, it is helpful to know the class of device(s) included in the request.

For assistance in determining your device class, visit the product classification database (see Appendix) or email dsmica@cdrh.fda.gov

Choosing a Certificate Type

- Class I - Devices are subject to the least regulatory control and have minimal potential harm to the user.

  Includes medical devices, such as

  – elastic bandages

  – examination gloves, or

  – hand-held surgical instruments.

Choosing a Certificate Type

- Class II - Devices for which require more regulatory control then Class I to assure safety and effectiveness

  Includes devices such as:

  – powered wheelchairs

  – infusion pumps

  – surgical drapes.

Choosing a Certificate Type

- Class III - Devices with the most regulatory control. Covers devices that usually support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury

  Includes devices such as:

  – Implantable pacemaker pulse generators
  – Silicone breast implants
  – Endosseous implants

Choosing a Certificate Type

- Certificate to Foreign Government
  - Cleared/approved for marketing in the U.S. or exempt
  - Commercially distributed in the U.S.
  - Class I, II, or III device
  - May be legally exported without a certificate
- Certificate of Exportability under Section 801(e)(1) of the FD&C Act
  - Class I or Class II device
  - Not approved for marketing in the U.S. and
  - May be legally exported without a certificate

Choosing a Certificate Type

- Certificate of Exportability under Section 802 of the FD&C Act
  - Class III device
  - Not approved for marketing in the U.S.
  - Establishments meet cGMP's
  - May be legally exported without a certificate

- Non-clinical research use only
  - Products used only in laboratory research animals, or tests in vitro not for use in humans or represented as an effective in vitro diagnostic product

Types of Certificates

- Certificate to Foreign Government
  - Devices are legally marketed in the U.S.
  - No restrictions to sale
  - Establishments are registered and devices are listed with FDA
  - Must meet any applicable labeling requirements
  - No open recalls

Types of Certificates

- Certificate to Foreign Government
  - Must be manufactured in accordance with the Quality Systems (QS) Regulation of 21 CFR Part 820 (also know as Good Manufacturing Practices or GMP), unless exempted by regulation
  - Must comply with the laws of the importing country

Types of Certificates

- Certificate of Exportability Under Section 801(e)(1)
  - Devices are NOT legally marketed in the U.S.
  - Establishments are registered and devices are listed with FDA
  - Would likely be a Class I or II or exempt if marketed in the U.S.
  - Not in conflict with laws of the importing country
  - Labeling requirements (export use only)

Types of Certificates

- Certificate of Exportability Under Section 802
  - Device is NOT legally marketed in the U.S.
  - Would likely be a Class III device if marketed
  - Establishments are registered and devices are listed with FDA
  - Device is manufactured under cGMP's - 802(f)(1) of the FD&C Act

Types of Certificates

- Certificate of Exportability Under Section 802
  - Not in conflict with laws of the importing country
  - Meets all labeling requirements (The shipping package for the device is labeled on the outside that it is intended for export; 801(e)(1).)
  - Device is marketed in a “Tier 1” country or is under investigational use in a “Tier 1” country.

Types of Certificates

Certificate of Exportability Under Section 802

- "Tier 1" countries include: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa or member countries the European Union or of the European Economic Area (EEA). Added in 2004 are: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia.

Other Conditions

- The device is not adulterated by containing any filthy, putrid, or decomposed substance; 501(a)(1).
- The device is not packed or held under unsanitary conditions; 501(a)(2)(A).

Types of Certificates

Certificate of Exportability Under Section 802 – Other Conditions

- Each device container does not contain any poisonous or deleterious substance; 501(a)(3).
- The device accords to specifications of the foreign purchaser; 801(e)(1).
- Not the subject of a notice by the Department of Human Services that re-importation would not pose an imminent hazard, nor pose an imminent hazard to the receiving country

Types of Certificates

- Certificate of Exportability Under Section 802 – Other Conditions
  - Not be mislabeled other than by possessing the language, units of measure, or any other labeling authorized by the recipient country. In addition, the labeling must comply with the requirements and conditions of use in the listed country which gave marketing authorization, and must be promoted in accordance with its labeling.

Types of Certificates

Certificate of Exportability Under Section 802

If firm is exporting under 802, they must provide written notification to FDA on the first initial shipment to a country (Simple Notification)

Notification includes:

- Type of device
- Product's trade name and model number
- Country to receive device

Exporting Unapproved Class III Devices

- When exporting an unapproved class III device, you must do one of the following:
  - Request a certificate of exportability under section 802 OR
  - Export the device without a certificate but provide written notification (Simple Notification) OR
  - Apply for an Export Permit

  (Unless it is exported for investigational use)

Exporting Unapproved Devices for Investigational Use (802(c))

- An unapproved device may be exported without FDA authorization for investigational use to any Tier I Country if it is in accordance with the laws of that country.
- Such devices are not required to meet the requirements of the IDE regulation.
- Exportation of an investigational device to any country other than a Tier I Country must be authorized by FDA [801(e)(2)].

Types of Certificates

- Non Clinical Research Use Only
  - Export of a product, material, component for non-clinical research use only
  - NOT intended for human use
  - Presently offered for sale in the U.S.

Export Permit (not a Certificate)

- If you meet the requirements, you MUST obtain from FDA prior to export. Some requirements are:
  - Not sold in the U.S.
  - Would be a Class III device if approved
  - No GMP inspection OR
  - Not Authorized for use in a “Tier 1” country or is under investigational use in “Tier 1” country

Requesting a Certificate

- Certificate to Foreign Government
  - FDA Form 3613 (Supplementary Information Certificate to Foreign Government Requests)
- Certificates of Exportability
  - FDA Form 3613a (Supplementary Information Certificate of Exportability Requests)
- Non Clinical Research Use Only
  - FDA Form 3613c (Supplementary Information Non-Clinical Research Use Only Certificate)

(See Appendix for links to these forms)

Requesting a Certificate

You will need:

- Name, address and registration number of all establishments on your sample certificate/attachment pages
- The marketing authorization # and dates for each device on your request requiring premarket authorization/clearance (PMA / 510(k))

Requesting a Certificate

- Federal Tax ID number of the requestor
- FDA recall number and date closed for any device on the request that is or was under recall
- Total number of certificates
- List of countries for which the certificates are being requested
- Date of last FDA inspection for any establishment on the request (if applicable)
- Signed Exporter's Certification Statement

Helpful Hints

Do’s

- Make sure that each establishment name and address that is on your sample certificate is also on your attachment pages
- Make sure that the headers used on the certificate are also on the attachment pages
- Be sure to fill out the form completely

Helpful Hints

Do's

- If you have more then one establishment listed on your certificate, you must submit a separate Exporters Certification Statement for each domestic manufacturer listed UNLESS they share ownership with the requestor OR they are a contract manufacturer
- Foreign firms can appear on certificate but the devices MUST be exported from the U.S.

Helpful Hints

Don’t:

- Don’t forget to sign and date the Exporter’s Certification statement in the form packet
- Do not send in a check with your certificates. You will be invoiced later by FDA
- Don’t forget to include the marketing status for each device in your request

Certificate Processing

- Mail the form along with any attachment pages to the address included in the form
- Your request is logged in and reviewed
- You will be contacted if there are any questions or missing data on your request
- After approval and quality review, it is printed, signed, notarized and mailed

Certificate Processing

- Costs
  - You will receive an invoice within four months after your request if filled – Do not submit payment with your request
  - Current costs are $175 for each original (maximum of 50 total pages / $175) and $15 for each copy requested at the time of processing
  - If you require a specific country on a certificate, the cost is $175 per certificate

Record Keeping

If exporting under section 801(e)(1) of the act:

- must maintain records demonstrating that the product meets the requirements of section 801(e)(1) of the act.
- Records must be retained for a period of time equivalent to the design and expected life of the device, but in no case less than two years from the date of release for commercial distribution by the manufacturer (21 CFR 820.180).
- The records must be made available to the Food and Drug Administration (FDA), upon request, during an inspection for review and copying by FDA.

Record Keeping

Records required to be maintained include the following:

- Records demonstrating that the product meets the foreign purchaser's specifications.
- Records demonstrating that the product does not conflict with the laws of the importing country.
- Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export:
- Records demonstrating that the product is not sold or offered for sale in the United States

Record Keeping

If exporting under section 802 of the act

- In addition to the requirements in 801(e)(1) noted above, such records include, but are not limited to, the following:
  - The product's trade name;·
  - The type of device;
  - The product's model number;
  - The consignee's name and address; and
  - The date on which the product was exported and the quantity of product exported.

Record Keeping

- These records shall be kept at the site from which the products were exported or manufactured
- Be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer (21 CFR 820.180).
- The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

Appendix

- Forms 3613, 3613a, 3613c can be found on the FDA forms site at:

www.fda.gov/AboutFDA/ReportsManualsForms/Forms/MedicalDeviceForms/default.htm

- Product Classification database at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm
- Email us at: exportcert@cdrh.fda.gov