Exporting Medical Devices

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Learning Objectives

1. Review background information on the Exports Program
2. Describe purpose of export documents
3. Identify certificate types and criteria
4. Describe export permit letter and simple notification
5. Explain steps to request export documents
6. Explain recordkeeping requirements for export documents

Background

- Foreign governments may ask establishments for an export certificate
- Medical devices legally marketed in United States (U.S) may be exported without notifying FDA

Background

Export Reform and Enhancement Act of 1996 authorizes:

- FDA to issue export certificates
- FDA to approve or deny a request
- Medical Device manufacturers to request a certificate for the medical devices they export

Background

Export Reform and Enhancement Act of 1996 authorizes:

- FDA to charge a fee for export certificates issued within 20 days
- Modification of Section 801 of Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Replacement of Section 802 of the FD&C Act

Purpose of Export Documents

Depending on its type, an export document may certify that the:

- Establishment is compliant with the FD&C Act
- Establishment conforms to Current Good Manufacturing Practices (CGMPs)
- The devices may be legally marketed in the United States

Types of Certificates

1. Certificate to Foreign Government (CFG)
2. Certificate of Exportability
    - under Section 801(e)(1)
3. Certificate of Exportability
    - under Section 802
4. Non-Clinical Research Use Only Certificate

Certificate Background

- Classification of device(s) must be known for request
- FDA registration and listing is required for some certificates
- Printed on special security paper
- Valid for two years from date certificate is issued

1. Certificate to Foreign Government

- Legally marketed devices in the United States
  - Class I, II, or III
  - Through premarket submission or exempt by regulation
- Establishments are registered with FDA
- Devices are listed with FDA

1. Certificate to Foreign Government

- Devices meet applicable labeling requirements
- Establishments have no open recalls
- Devices manufactured per Quality System Regulation of 21 CFR 820
  - unless exempt by regulation
- Establishments comply with laws of importing country

CFR = Code of Federal Regulation

2. Certificate of Exportability: Section 801(e)(1)

- Devices are NOT legally marketed in the United States
  - Class I, II or exempt devices
- Establishments are registered
- Devices may be listed with FDA
- Comply with laws of importing country
- Device labeled as “intended for export” or “for export only”

3. Certificate of Exportability: Section 802

- Devices meet performance standards per Section 514 of the FD&C Act
  - for Class II and III devices not legally marketed
- Establishments are registered
- Devices may be listed with FDA
- Devices are in accordance with specifications of foreign purchaser

3. Certificate of Exportability: Section 802

- Establishments comply with laws of importing country
- Devices are marketed in the countries listed in Section 802 (b)(1)(A)(i) and (ii) of the FD&C Act
- Devices are under investigational use in those countries
- Device labeled as “intended for export” or “ for export only”

3. Certificate of Exportability: Section 802

- Establishments substantially conform to CGMPs
- Device is not adulterated
- Reimportation of device does not pose an imminent hazard to the U.S. or the receiving country

4. Non-Clinical Research Use Only Certificate

- Export of product, material or component for non-clinical research use only
- NOT intended for human use
- Marketed in, and legally exported from, the United States
  - per FD&C Act

Other Types of Export Documents

FDA also:

- Issues Export Permit Letters (EPL)
  - per Section 801(e)(2)
- Receives Simple Notifications
  - per Section 802(g)

Export Permit Letter
Section 801(e)(2)

Issued for devices that are:

- Class III, investigational
- According to specification of foreign purchaser
- Not in conflict with laws of country to which it is intended for export
- Not approved for marketing and not sold or offered for sale in the U.S.

Export Permit Letter
Section 801(e)(2)

Issued for devices that are:

- Labeled “intended for export” or “for export only”
- Not in compliance with Section 514 (performance standards) of FD&C Act
- CGMP inspection not required

Export Permit Letter
Section 801(e)(2)

Issued for devices that are:

- Unapproved
  - PMA not submitted to/approved by FDA
- Don’t meet criteria under Section 802
- Not Authorized for marketing in a country listed in Section 802 (b)(1)(A)(i) and (ii) of the FD&C Act
- Not under investigational use in a country listed in Section 802 (b)(1)(A)(i) and (ii) of the FD&C Act

Export Permit Letter
Section 801(e)(2)

- No fee is charged for an Export Permit Letter
- FDA is not required to issue Letter within 20 days

Export Permit Letter

Exporting Unapproved Devices for Investigational Use 802(c)

- May be exported without FDA authorization to any country listed in Section 802(b)(1)(A)(i) and (ii) if in accordance with laws of that country
- Not required to meet the requirements of the Investigational Device Exemption (IDE) regulation
- Exportation to any country other than the countries listed in Section 802(b)(1)(A)(i) and (ii) must be authorized

An Export Permit Letter is appropriate if an export document is needed.

Simple Notification
Section 802(g)

- Required when exporter begins to first export a device to:
  - Countries listed in Section 802(b)(1)(A)(i) and (ii)
  - Countries NOT listed in Section 802(b)(1)(A)(i) and (ii)
- No certificate is issued; Acknowledgement Letter provided
- No fee is required
- FDA Acknowledgment Letter not required to be issued within 20 days

Simple Notification
Section 802(g)

Per 21 CFR 1.101 (d), Notification must identify:

- Product's trade name
- Type of device
- Product's model number
- Country to receive exported article, if not listed in 802(b)(1)

Simple Notification
Section 802(g)

Notification may:

- Identify country listed in 802(b)(1)(A); or
- State that export is intended for a listed country without identifying the listed country

How to Request an Export Document

I. Electronically:

- Must register establishment with FDA via FDA Online Account (FDA OAA)
- FDA OAA account ID and password may be used to access or create subaccounts for CDRH Export Certification and Tracking System (CECATS)
- CECATS may be accessed after logging into the FDA Unified Registration and Listing Systems (FURLS)

How to Request an Export Document

I. Electronically:

- Information you may need:
  - Registration or owner operator number of all establishments involved with the manufacturing of the devices
  - The marketing authorization number and dates for each device to be included on your request requiring premarket authorization/clearance (PMA / 510(k))
  - Federal Tax ID number of the requestor

How to Request an Export Document

I. Electronically:

- Information you may need:
  - FDA recall number and date closed for any device on the request that is or was under recall
  - Total number of certificates needed
  - List of countries for which the certificates are being requested

How to Request an Export Document

II. Contact Export Staff for assistance:

- Email: Exportcert@cdrh.fda.gov or CDRHCECATS@fda.hhs.gov
- Telephone: 301-796-7400 and select Option 3

How to Request an Export Document

- Certificates issued within 20 business days if applicable requirements are met
- Fee for export certificates issued from CDRH
- Do not submit payment with export document request
- No fees associated with export permits and simple notification
- Invoices are generated after each fiscal quarter for certificates issued within 20 days

How to Request an Export Document

- Each certificate is limited to 25 pages
- The name of foreign firms can appear on the certificate
- Separate application must be submitted for each country on each certificate
- Application will be returned for action if questions or concerns during the review process
- If you do not respond, you must submit a new application
- Please respond as directed within 48 hours

Recordkeeping

For exporting under Section 801(e)(1) of the FD&C Act:

- Must maintain records demonstrating that product meets requirements of Section 801(e)(1) of the FD&C Act
- Records must be retained for same period of time as required by 21 CFR 820.180
- Records must be made available to FDA upon request

Recordkeeping

For exporting under Section 802 of the FD&C Act:

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

Recordkeeping

For exporting under Section 802 of the FD&C Act:

- Maintain records [Section 802(g)] of all devices exported and the countries to which the products were exported
- Records must be kept at the site from which the products were exported or manufactured
- Records must be retained for the same period of time as required by 21 CFR 820.180
- The records must be made available to FDA, upon request during an inspection, for review and copy by FDA

Summary

- Legally marketed devices in the U.S. may be exported without prior FDA notification
- CDRH will only issue export certificates for medical devices
- Requests are submitted using CECATS
- CDRH issues permit letters and receives simple notifications for exporting devices

Your Call to Action

- Register applicable facilities listed on the export document request
- Respond to CDRH as directed within 48 hours

Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - over 125 modules
   - videos, audio recordings, power point presentations, software-based “how to” modules
   - mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/Training/CDRHLearn

2. **Device Advice: Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE


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