Import and Export Requirements for Medical Devices

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FDA's AUTHORITY OVER THE IMPORT & EXPORT OF MEDICAL DEVICES

Imports:

- **Section 801(a) - (d) of the FD&C Act**
- **21 CFR Part 800 – Medical Device Regulations**

Exports:

- **Section 801(e) of the FD&C Act**
- **Section 802 of the FD&C Act**

http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm

Import Requirements

For Medical Devices

REQUIREMENTS TO LEGALLY MARKET DEVICES IN THE U.S.

- Establishment Registration
- Medical Device Listing
- Compliant Labeling
- Quality Systems/GMP
- Appropriate Marketing Applications
  - 510(k)
  - PMA
  - None (pre-amendment or exempt)

SECTION 801(a)

- U.S. Customs & Border Protection (CBP) will notify U.S. FDA regarding the entry of regulated products, which includes medical devices.

IMPORT PROCEDURES

- U.S. Importer posts bond, may pay duty, and obtains permit from U.S. CBP
- U.S. CBP electronically submits invoices of regulated products to FDA
- FDA decides whether to examine and/or sample shipment , or to release shipment without examination

SAMPLING DECISIONS

- FDA sets sampling priorities
- Approx. 10% products sampled; 90% released without examination
- Guidance to Districts for some devices
- Examination may be visual (labeling) or laboratory analysis
- Some products are 100% sampled, e.g. condoms, gloves

PRODUCT EXAMINED OR SAMPLED

- If shipment passes examination – Admitted
- If shipment fails – Entry denied and detained
- Detained shipment:
  - May be moved to nearby warehouse
  - Requires FDA (not CBP) Release for destruction, re-export, or reconditioning.
- If reconditioning passes – Entry allowed
  - Reconditioning fails – destroy or re-export

FDA AUTOMATED ENTRIES

OASIS System (**O**perational and **A**dministrative **S**ystem for **I**mport **S**upport)

- Broker enters data into the CBP System
- If it is a device, CBP prompts Broker
- Broker enters OASIS system, and enters data
- OASIS System makes a risk assessment based on Broker's data – shipment released, or, shipment detained for examination

FDA REGULATIONS – 21 CFR

- General Device Labeling (801)
- In-vitro Diagnostic Labeling (809)
- Marketing Clearance [510(k) and PMA]
- Registration and Listing (807)
- U.S. Agent (807)
- Quality System (820)
- Radiation emitting products (1002)

MANUFACTURER RESPONSIBILITIES

- Obtain Marketing Clearance
- Register Establishment as Manufacturer
- Appoint U.S. Agent
- List Device(s)
- Establish and Maintain Quality System
- Comply with other applicable regulations
  e.g. radiation controls

IMPORTER RESPONSIBILITIES

- Register Establishment as Initial Distributor
- Take title to goods
- Act as agent for investigational devices and,
  - act as sponsor of the clinical trial (IDE); or
  - ensure another party acts as agent/sponsor

IMPORT FOR EXPORT

- Section 801(d)(3) permits U.S. firms to import components, subassemblies, unfinished devices to the U.S. for the purpose of "further processing" or "incorporation" (to include packaging labeling or sterilization) into medical devices which are not approved for marketing in the U.S. - for subsequent export from the U.S.
- Operations require registration, and listing, and are subject to FDA audits
- Statement for intent to export must be supplied to FDA

FOR MORE INFORMATION ON IMPORTS PLEASE CONTACT:

FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
DIOP, HFC-120
5600 FISHERS LANE
ROCKVILLE, MD 20850

FDA/CDRH/OFFICE OF COMPLIANC
IMPORT STAFF
10903 NEW HAMPSHIRE AVE.
SILVER SPRING, MD 20993

Export Requirements

For Medical Devices

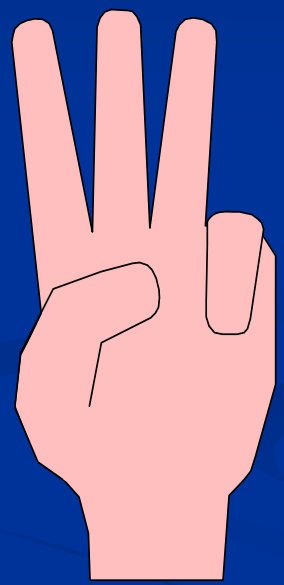
EXPORT OF LEGALLY MARKETED DEVICES

- **No FDA paperwork is necessary to export; however:**
  - **some countries require written proof of product compliance with U.S. law**
- **FDA will furnish a Certificate for Foreign Government (CFG)**
  - upon exporter's request
  - device must be legally marketed in U.S.

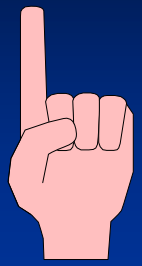
HOW DO U.S. FIRMS EXPORT MEDICAL DEVICES THAT ARE NOT LEGALLY MARKETED IN THE UNITED STATES?

FDA'S EXPORT PROVISIONS ARE THREE TIERED:

1. Section 801(e)(1)
2. Section 801(e)(2)
3. Section 802



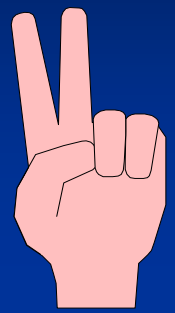
SECTION 801(e)(1)



Class I or II devices can be exported if:

- Device meets purchaser's specifications,
- Device is not in conflict with the laws of the foreign country,
- Device is properly labeled for export, and,
- Device is not, nor has been, sold in the U.S.

SECTION 801(e)(2)



The export of certain devices not marketed in the U.S. are subject also to section 801(e)(2) (not widely used) and/or 802

- Unapproved devices which would require a PMA
- Investigational devices (clinical trials)
- Banned devices

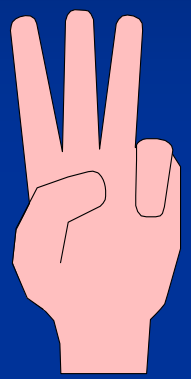
SECTION 801(e)(2)

- Exports must first satisfy the provisions of 801(e)(1)
- Exporter must obtain a letter of acceptance from the foreign liaison permitting export to the country (CE mark is acceptable for EU),
- FDA must approve the export request
- FDA is required to assure that export is not contrary to public health or safety

801(e)(2) (Cont'd)

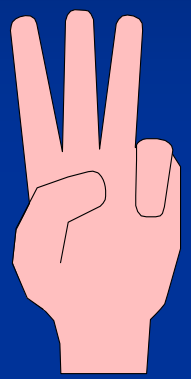
- FDA permission to export can be denied for:
  - Improper letter of acceptance
  - Safety or regulatory problems
- Or - the unapproved device may qualify for export under section 802

SECTION 802



Under certain conditions, medical devices approved for marketing in a "tier 1" country may be exported under section 802 as an alternative to obtaining FDA permission to export under 801(e)(2)

Tier 1 Countries



Australia, Canada, New Zealand, Japan, Israel, Switzerland, South Africa, or member countries of the EU or European Economic area. Added in 2004 are Cyprus, Czech Republic, Estonia, Hungry, Lithuania, Latvia, Malta, Poland, Slovakia, Slovenia. HHS can add others.

Conditions for export under Section 802 - qualified under Section 802 (f)

- device must meet QS (Part 820) or another FDA recognized international GMP standard,
- requires U.S. exporters to meet the provisions of 801(e)(1),
- not be adulterated other than by lack of a U.S. marketing approval and,
- be labeled in accordance with the country's marketing authorization

SECTION 802(g)

- Prior to export under section 802, the exporter shall provide FDA, CDRH (HFZ-307) with a "simple notification", identifying the name of the firm and the device, the first time that the firm exports the device to a new country
- One way - prior approval by FDA is not required prior to export

FOR MORE INFORMATION ON EXPORTS PLEASE CONTACT:

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

RPSB

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

exportcert@cdrh.fda.gov