FDLI Introduction to Medical Device Law and Regulation – International Issues

Sarah H. Stec
Johnson & Johnson
sstec@its.jnj.com

Agenda

- Exporting Medical Devices
  - Approved Devices
  - Unapproved Devices:
    - Export under 801(e)(1) and 801(e)(2)
    - Export under 802
  - Investigational Devices
  - Certificate of Exportability (COE), Certificate of Foreign Government (CFG)
- Importing Medical Devices
  - Roles of FDA and CBP, Inspections
  - Import Alerts and Detentions
  - Reconditioning or Destruction
  - Import for Export

Exporting Approved/Cleared Medical Devices

Meet the receiving country's requirements for importing your medical device.

- If the country requires a Certificate of Foreign Government (CFG), then you can request one.

We'll talk more about CFGs later…

Exporting Unapproved Medical Devices

Before the FDA Export Reform and Enhancement Act of 1996 (ERHA), manufacturers had to get FDA's approval that the device would not be "contrary to the public health and safety," and that the device had the approval of the receiving country.

- This provision is still there in case you have to use it - § 801(e)(2)

The ERHA created **many more** pathways for manufacturers to export their unapproved devices by amending § 801(e)(1) and providing a potential path through § 801(e)(2): § 802

Exporting Unapproved Medical Devices

FD&C § 801(e)(1) A medical device intended for export is not adulterated or misbranded if it:

- Meets the foreign purchaser's requirements;
- Is not in conflict with the laws of the country of export;
- Is labeled on the outside of the shipping package that it is intended for export; and
- Is not sold or offered for sale in domestic commerce

FD&C § 801(e)(2): This section (801(e)(1)) does not apply to:

- Class III devices
- Class III devices subject to performance standards
- Banned devices
- Investigational Devices

How can you export these devices? As long as FDA does not find the device to be contrary to public health and safety and is approved in another country, ***or § 802...***

Exporting Unapproved Medical Devices

FD&C § 802: Medical devices that:

- Comply with 801(e)(1) (802(f)(3)),
- Have received a marketing authorization from a Tier 1 country (802(b)),
- Intended for investigational use in a Tier 1 country (802(c)) (*See also* 21 CFR 812.18)
- Intended for further processing in anticipation of market authorization in a Tier 1 country (802(d)), or used in the diagnosis, prevention, or treatment of a tropical disease/not of significant prevalence in the US (802(e))
- Manufactured in substantial conformity with QSRs (802(f)(1))
- Not adulterated (802(f)(2)) or misbranded in the receiving country (802(f)(5) and 802(f)(6)
- Not subjected to determination that the probability of reimportation would present an imminent hazard to the public health and safety of the US or the country to which it is exported (802(f)(4))

May be exported even if the device is not approved/cleared.

Exporting Unapproved Medical Devices

But what if I need to export to a country that isn't on the Tier 1 List at § 802(b)(1)(A)?

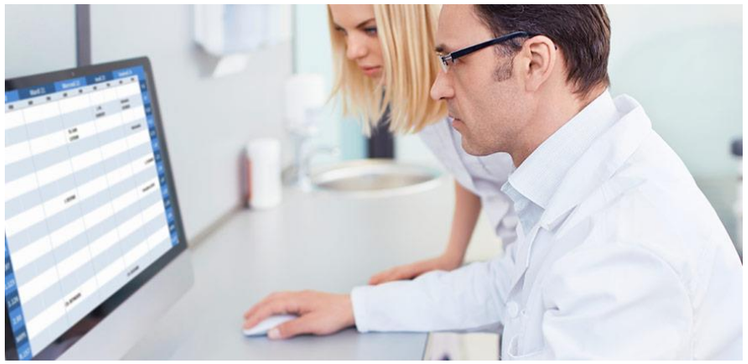
Is the device approved in a Tier 1 country?

No…

Request approval from FDA using § 801(e)(2).

Yes, but I want it to go somewhere else.

You can still use § 802 – "A . . . Device . . . May be exported to **any** country, if the drug or device complies with the laws of **that** country **and** has valid marketing authorization by the appropriate authority [in a Tier 1 country]."



Exporting Unapproved Medical Devices

Documentation Requirements

If exporting under § 802, Exporter must provide a simple notification to FDA when first exporting:

- Trade name of the device
- Type of device
- Product model
- Country to which the device is being exported

Exporters must maintain records of all devices exported and the countries to which they were exported.

Export Certificates

Export Certificates are prepared by FDA and contain information about a product's regulatory or marketing status in the US

Certificate of Foreign Government (CFG) is for devices that may be legally marketed in the US (you have either a PMA or a 510(k))

Certificate of Exportability is for devices that may not be legally marketed in the US and that meet the requirements of § 801(e)(1) (COE 801) or § 802 (COE 802)

Export Permit Letter is for devices that use the mechanism at § 801(e)(2)

Non-Clinical Research Use Only Certificate is for products, materials, or components that are not intended for human use that may be marketed in and legally exported from the US.

To request all of these certificates, use CECATS and follow the instructions for each type of certificate. You can request access to CECATS once you create a FURLS account.

Also use CECATS to notify FDA of an export to a Tier 1 country under § 802

Importing Medical Devices

FD&C Act § 801: Imports and Exports:

"(a) The Secretary of the Treasury [CBP] shall deliver to the Secretary of Health and Human Services [FDA], upon his request, samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States . . . [FDA] shall furnish to [CBP] a list of **establishments registered** . . . And shall request that if any drugs, devices, or tobacco products manufactured, prepared . . . in an establishment not so registered are imported or offered for import into the United States, samples of such drugs, devices or tobacco products be delivered to the [FDA] with notice of such delivery to the owner or consignee, who may appear before the [FDA] and have the right to introduce testimony."

If it *appears* from the examination of such samples or otherwise that:

- "the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of [GMP]";
- The device is banned in the country from where it was exported;
- The product is adulterated or misbranded;

The article is refused admission. (And there's more, but it's mostly on food and drugs)

Importing Medical Devices

That was a lot…what does it mean?

- FDA can examine any shipment, not simply the ones that contain devices
  - There are many products that aren't medical devices somewhere else, but are medical devices in the US
- Even if the product ***is*** compliant, if it ***appears*** noncompliant, FDA ***shall*** refuse the shipment
  - Devices are expected to be in compliance at the time of entry
    - Processing is allowed, but this must be declared at the time of importation
- The owner and/or consignee can offer testimony and appear before FDA regarding the product's compliance
  - "Owner" and "consignee" are strictly defined – If the manufacturer isn't the "owner" or "consignee" of the shipment, then the manufacturer does not have the right to offer testimony or to an appearance.

Importing Medical Devices

Two Agencies involved with importing medical devices: FDA and CBP. Medical devices must meet regulatory requirements for both agencies:

- CBP administers assessments and collection of all duties, taxes, fees, reviewing import forms, and enforcing CBP and related laws
  - Automated Commercial Environment (ACE) is a CBP system
- FDA reviews entries for FDA-regulated products
  - CBP verifies establishment registration, product regulatory status with FDA before allowing the product to enter

Importing Medical Devices

Importation Process

1. Entry is made to CBP, and CBP's Automated Commercial Environment (ACE) system forwards the entry to FDA's PREDICT system for review (CBP issues a "conditional release", which is a release from CBP custody but not from the terms and conditions of CBP's bond).

2. FDA reviews the entry for conformity with requirements (clearances/approvals, establishment registration and device listing), the history of the commodity or manufacturer (import alerts/bulletins, any other local intelligence), and compares against compliance programs and assignments.

3. FDA will decide to either release the devices, detain without examination, or obtain more information (sample collection, document examination).

4. Examining the documentation results in FDA deciding to Release the shipment, Detain the shipment, or Examine or sample the shipment.
    1. Released shipments – Can continue on their way
    2. Examination/Sample Collection – FDA examines samples, can request CBP issue order for redelivery if shipment not already made available to FDA
    3. Detention – Detention and Hearing Process

Import Alerts and Detentions

Import Alerts – Products that are subject to refusal unless the importer can ensure that the products are in compliance with US laws

- **Uniform coverage across the country –** Import alert equally applicable at LAX, IAD, MIA, etc.
- Some ways to get on the Import Alert list:
  - Products subject to Detention Without Physical Examination
  - Inspections of foreign establishment(s) that find QSR violations
  - Other intelligence sources (foreign governments, states, etc.)
- Can apply to a specific manufacturer or to a specific product, can also apply to a country or region

Import Alerts and Detention

Detention Without Exam – Importer can give evidence to refute the appearance of a violation

- FDA will take evidence and the detention will either stand (and be **refused**) or be overturned (and **released**)
- Importer can also petition to **recondition** the goods to bring them into compliance (i.e. relabeling, cleaning an adulterated product, etc.)
  - Reconditioning must be approved by FDA; see 21 CFR 1.95, 1.96
- *How do you get a detained product out of detention?*
  - Adequate remedial actions
  - Verification through evaluation of actual entries
  - Assurance that the cause of the violation has been corrected; and
  - Assurance of consistent compliance

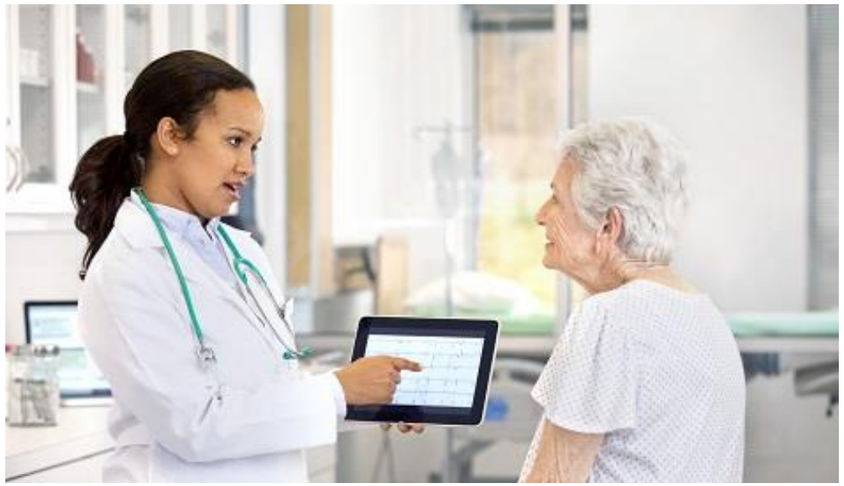
Destruction and Reconditioning

Upon detention, FDA sends a notice ("Notice of FDA Action – Detained") that the imported product may be subject to destruction and gives the owner a **time and place for a hearing**. The owner may testify as to how they plan to **recondition** the product.

If the owner submits a detailed application for **reconditioning or relabeling** and if FDA approves the application, the owner has a specific time limit within which to complete the required actions. *See* 21 CFR 1.95, 1.96. If the reconditioning or relabeling conditions have been fulfilled, then CBP and FDA will release the product!

If the reconditioning or relabeling conditions are not fulfilled, FDA may refuse the entry, and the article is **destroyed** or **exported** under CBP's supervision within 90 days.

Importing Investigational Devices



Investigational Devices may be imported if there is an Investigational Device Exemption (IDE) for the device. This means:

- IDE and compliance with 21 CFR Part 812
  - Preliminary criterion: There is a clinical investigation **in the US** to determine the safety and effectiveness of a medical device
- The Device is labeled correctly
  - "CAUTION – Investigational Device. Limited by Federal (or United States) law to investigational use."
- Sponsor is located in the US
  - "A person who imports or offers for importation an investigational device . . . Shall be the agent of the foreign exporter with respect to investigations of the device and **shall act as the sponsor of the clinical investigation**, or ensure that another person acts as the agent of the foreign exporter and the sponsor of the investigation." 21 CFR 812.18(a).

Import for Export

FD&C Section 801(d)(3) allows importation of certain unapproved or otherwise noncompliant devices for further processing or incorporation into other products that will be exported from the US.

- Only applies to **components** of devices – Needs to be credible that the product is intended for further processing (can't be a finished device).

- Conditions that must be met:
  - Importer submits a statement that provides that (1) the device is intended to be further processed or incorporated into a device, (2) identifies the manufacturer and each processor, packer, distributor, or other entity that had possession between the manufacturer and the importer, and (3) is accompanied by any necessary certificates of analysis.
  - Owner/consignee executes a bond for liquidated damages
  - **The article is actually used and exported by the initial importer or consignee in accordance with the intent described, except for any portion that is destroyed**
    - **Can't change your mind!**
  - Owner/consignee maintains records on the use or destruction of the article and submits to FDA upon request.

Thank you.