

# Imports and Exports

## AMDM Conference

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# Imports and Exports

## Important Statutes

Food and Drug Administration Amendments  
Act of 2007

Export Reform and Enhancement Act of 1996

# Electronic Registration and Listing

## New Requirements in Effect Now

- Electronic submission of registration and listing information using the Internet
- Time frame to register
- User fees for initial and annual registration

# Electronic Registration and Listing

## New Requirements (cont.)

- Annual updating of listing information
- Supply 510(k) number
- Product code for devices exempt from premarket submissions

# Electronic Registration and Listing

## New Requirements (cont.)

- Type of operations, e.g.,  
manufacture, repackaging, relabel
- Registration and listing contact at the  
owner or operator site

# Electronic Registration and Listing

## New: Registration and Listing

Foreign Manufacturers

### New: Listing

Domestic contract manufacturers /  
sterilizers that place devices into  
commercial distribution

# Electronic Registration and Listing

## Electronic Registration

Internet based system

Homepage site:

<http://www.fda.gov/cdrh/reglistpage.html>

# Electronic Registration and Listing

## Electronic Registration Waiver

FDA may grant individual requests upon finding that electronic means is not feasible for the person requesting the waiver.

# Electronic Registration and Listing

## Timeframe

Initial: 30 days after beginning activity

Renewal: October 1 through December 31. It covers the next calendar year, For example, registration on December 2008 covers calendar year 2009.

# Electronic Registration and Listing

## Information to Submit

- Name of owner / operator of each establishment
  
- Foreign firms:
  - US agent
  - Known importers or those that offer

# Electronic Registration and Listing

## User Fee

- All establishments pay a flat fee -

<u>Fiscal Year</u>	<u>Fee</u>
2008	\$1,706
2009	1,851
2010	2,008
2011	2,179
2012	2,364

# Electronic Registration and Listing

Payment by Check

Mailing address:

Food and Drug Administration  
P.O. Box 70961  
Charlotte, NC 28272-0961

# Electronic Registration and Listing

## Payment by Wire Transfer

US Dept of Treasury  
TREAS NYC  
33 Liberty St  
New York, NY 10045

# Electronic Registration and Listing

## Payment Instructions

<http://www.fda.gov/cdrh/reglistpage.html>

“Fees and Payments”

# Electronic Registration and Listing

## Next Steps

Proposed Rule

Draft Guidance

# Exporting devices not marketed in the US

## FDA Export Reform and Enhancement Act of 1996

Exporting devices not marketed in the US:

Amends Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 USC 381)

- Section 801 (Old Way)
- Section 802 (*New Way*)
- Import for Exports
- Certificates

# Exports: Big Issues

- 1 Devices *legally marketed* devices in the US  
(same old way)
- 2 Devices *not legally marketed* in the US  
(old and *new way*)
- 3 Certificates: two types  
(old and *new way*)
- 4 Import for Export only (*new way*)

# Exporting devices legally marketed

- Devices legally marketed in domestic commerce (old way)
- Export them without notice to FDA
- Certificate to Foreign Governments (CFG)

# Certificate to Foreign Government Want one?

## Self-certification Checklist:

- Manufacturer is registered and listed.
- Premarket clearance / approval.
- Manufacturer complies with cGMP\*

\*No GMP history? – OK. We'll edit the CFG.

Remarketed (used) device? – sorry.

# Exporting devices not legally marketed in the US.

- Two options:
  - Section 801(e)(1) – the old way
  - Section 802 – the new way

# Exports under section 801(e)(1) (The Old Way)

- These statutory criteria always apply – for both old and new ways of exporting.
  - 1) Meet foreign purchaser's spec's;
  - 2) Not in conflict with the laws of foreign country;
  - 3) Shipping carton labeled for export; and
  - 4) **Not offered or held for sale in domestic commerce!**

# Exports under 801(e) (Old Way)

- 801(e)(1) for class II type devices
- The benefits:
  - Enforcement discretion on notice requirement
    - “Just do it.”
  - No cGMP requirement
  - “Exportability” Certificate as an OEM

# Export under 801(e)(1) (Old Way)

- Certificate of Exportability
  - Device subject to FDA jurisdiction
  - Device may not be sold or offered for sale in the US
  - Meets the four export criteria of 801(e)(1)

# Exports under 802 (New Way)

- Any unapproved device (class III)
- Tier I country clearance required
- Must meet 801's four criteria
- Requires substantial compliance with cGMP - section 802(f)

# Exports under 802 (New Way)

- Again, always meet “old” statutory criteria:
  - 1. Purchaser's specifications
  - 2. No conflict with foreign country's law
  - 3. Shipping container labeled for export
  - 4. Not sold or held for sale in domestic commerce
- Try to Remember Please (P-L-E-S)...

# Exports under 802 (New Way)

## ■ Tier I countries

- Australia
- New Zealand
- Canada
- South Africa
- Israel
- Japan
- Switzerland

## ■ European Economic Area



# 802 -European Economic Area

Austria  
Belgium  
Cyprus  
Czech Rep.  
Denmark  
Estonia  
Finland  
France  
Germany

Greece  
Hungary  
Iceland  
Ireland  
Italy  
Latvia  
Lithuania  
Liechtenstein  
Luxembourg

United Kingdom

Malta  
Netherlands  
Norway  
Poland  
Portugal  
Slovakia  
Slovenia  
Spain  
Sweden

More to come as the EU / EEA expands.

# Exports under 802 (New Way)

- What's substantial compliance with GMPs?
  - Last GMP inspection not classified as “Official Action Necessary,” e.g.,
    - Warning Letter
    - Injunction – related to device

# Exports under 802 (New Way)

## ■ Benefits

- Faster
- Identify device one time and go
- Worldwide commerce
- Covers commercial, investigational, and pipeline use.

# Exports under Section 802 (New Way)

- Certificate of Exportability –
  - Meets old export requirements (sec. 801(e)(1))
  - Device subject to FDA jurisdiction
  - Not approved for marketing in US
  - Manufacturing site subject to FDA inspection
  - Substantial compliance with cGMP

# “Import for Export” New Export Program!

- Section 801 (d)
- Purpose
  - Import for further manufacturing, then export (Jobs)
  - Conditional entry for articles otherwise refused entry (adulterated or misbranded)

# Import for Exports

Three main elements\*

- 1) Notice
- 2) Records
- 3) Export or destroy

\*Free Trade Zone – no exemption  
from Registration and Listing

# Notice - Imports for Exports

- To FDA District Office (import entry)
- Entry for further manufacturing by initial owner or consignee
- Statement by initial owner / consignee
- Into a device / subassembly for export
- Identify export authority (801 or 802)

# Records – Imports for Exports

- Maintain records that identify use of the components
  - Serial numbers or lot numbers, etc.
  - Activities related to the “processing.”
  - Identify location / possession.
- Upon FDA’s request, submit report that accounts for disposition of incoming articles
- 100% Accountability

# Export or Destroy

- Any component or accessory not incorporated into a device
- Reasonable time limitation
  - Note: US Customs Port Director may have time preference...
- Prohibited Act – Section 301 (w):
  - False statement
  - Domestic diversion

# Regulatory Follow-Up

- Deny Entry into the US
- Warning Letters
- No Certificates
- Seizure
- Civil Money Penalties
- Administrative Detention

# More Information?

- Check FDA's Internet site for "Exports"

<http://www.fda.gov/cdrh/index.html>

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