- Medical Device Imports - Safety Initiatives

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US Food and Drug Administration

New FDA Device Law: Impact on Imports

- Food and Drug Administration Amendments Act of 2007 (FDAAA)
  - Registration (Sec. 222)
  - Unique device identification (Sec. 226)
  - Third Party Inspections (Sec. 228)

Registration:
Electronic Registration and Listing

- 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

- Updating of listing information
- Premarket submission number
- Product code for devices exempt from premarket submissions

Electronic Registration and Listing

- Type of operations, e.g., manufacture, repackage, relabel, initial importer, etc.
- Registration and listing contact at the owner or operator site / US Agent

Electronic Registration and Listing

Foreign manufacturers must register

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Electronic Registration and Listing

Electronic Registration

Internet based system

Homepage site:
http://www.fda.gov/cdrh/reglistpage.html

Electronic Registration and Listing

Waiver from Electronic Registration?

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 -

Fiscal Year	Fee
2008	$1,706
2009	1,851
2010	2,008
2011	2,179
2012	2,364

Electronic Registration and Listing

Payment Instructions

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

“Fees and Payments”

Electronic Registration and Listing

...Next Steps...

Remove Firms from Active Database
(Denial of Entry for Products)

Issue Proposed Rule

Issue Draft Guidance

Unique Device Identification System (UDI)

- Device label bears a unique identifier
- Identifies device through distribution and use
- Includes the lot or serial number, if specified by FDA
- New regulations required

Third Party Inspections

- Multipurpose risk based inspectional obligations, e.g., FDA, ISO, EU
- Special Pilot with Canada
- Indicates a firm's compliance profile

Medical Device Imports

Questions and Comments

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