Medical Device Imports - Safety Initiatives

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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

* * * *
Electronic Registration and Listing

Electronic Registration

Internet based system

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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Fee</th>
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<tbody>
<tr>
<td>2008</td>
<td>$1,706</td>
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<tr>
<td>2009</td>
<td>1,851</td>
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<tr>
<td>2010</td>
<td>2,008</td>
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<td>2012</td>
<td>2,364</td>
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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Issue Draft Guidance
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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