Medical Device Recalls

Ron Brown
Chief, Recall Branch
Division of Analysis and Program Operations
Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
Objectives

- CDRH Recall Classifications and Trends
- Distinguishing Medical Device Recalls from Medical Device Enhancements
- Effective Recall Communication
### Number of Recalls by Class

<table>
<thead>
<tr>
<th>Year</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>5</td>
<td>350</td>
<td>106</td>
<td>461</td>
</tr>
<tr>
<td>2004</td>
<td>25</td>
<td>456</td>
<td>145</td>
<td>626</td>
</tr>
<tr>
<td>2005</td>
<td>25</td>
<td>414</td>
<td>128</td>
<td>567</td>
</tr>
<tr>
<td>2006</td>
<td>22</td>
<td>498</td>
<td>134</td>
<td>654</td>
</tr>
<tr>
<td>2007</td>
<td>26</td>
<td>538</td>
<td>96</td>
<td>660</td>
</tr>
<tr>
<td>2008</td>
<td>14</td>
<td>707</td>
<td>108</td>
<td>829</td>
</tr>
<tr>
<td>2009</td>
<td>32</td>
<td>661</td>
<td>65</td>
<td>758</td>
</tr>
<tr>
<td>2010</td>
<td>49</td>
<td>754</td>
<td>74</td>
<td>877</td>
</tr>
<tr>
<td>2011</td>
<td>50</td>
<td>1152</td>
<td>69</td>
<td>1271</td>
</tr>
<tr>
<td>2012</td>
<td>57</td>
<td>1043</td>
<td>91</td>
<td>1191</td>
</tr>
<tr>
<td>2013</td>
<td>69</td>
<td>1010</td>
<td>67</td>
<td>1146</td>
</tr>
<tr>
<td>2014</td>
<td>63</td>
<td>1171</td>
<td>49</td>
<td>1283</td>
</tr>
</tbody>
</table>

**Number of Recalls by Year**

- **Class I**
  - 2003: 5
  - 2004: 25
  - 2005: 25
  - 2006: 22
  - 2007: 26
  - 2008: 14
  - 2009: 32
  - 2010: 49
  - 2011: 50
  - 2012: 57
  - 2013: 69
  - 2014: 63

- **Class II**
  - 2003: 350
  - 2004: 456
  - 2005: 414
  - 2006: 498
  - 2007: 538
  - 2008: 707
  - 2009: 661
  - 2010: 754
  - 2011: 1152
  - 2012: 1043
  - 2013: 1010
  - 2014: 1171

- **Class III**
  - 2003: 106
  - 2004: 145
  - 2005: 128
  - 2006: 134
  - 2007: 96
  - 2008: 108
  - 2009: 65
  - 2010: 74
  - 2011: 69
  - 2012: 91
  - 2013: 67
  - 2014: 49

**Total**

- 2003: 461
- 2004: 626
- 2005: 567
- 2006: 654
- 2007: 660
- 2008: 829
- 2009: 758
- 2010: 877
- 2011: 1271
- 2012: 1191
- 2013: 1146
- 2014: 1283
# Top Recall Regulatory Violations: 2014

<table>
<thead>
<tr>
<th>Number</th>
<th>Regulation Subpart Title</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>820.30</td>
<td>Design controls</td>
<td>703</td>
<td>1,759</td>
<td>36</td>
</tr>
<tr>
<td>820.80</td>
<td>Receiving, in-process, and finished Device acceptance</td>
<td>204</td>
<td>1,068</td>
<td>61</td>
</tr>
<tr>
<td>820.70</td>
<td>Production and process controls</td>
<td>119</td>
<td>830</td>
<td>58</td>
</tr>
<tr>
<td>820.90</td>
<td>Nonconforming product</td>
<td>17</td>
<td>415</td>
<td>28</td>
</tr>
<tr>
<td>820.75</td>
<td>Process Validation</td>
<td>16</td>
<td>390</td>
<td>30</td>
</tr>
<tr>
<td>820.50</td>
<td>Purchasing controls</td>
<td>19</td>
<td>366</td>
<td>29</td>
</tr>
<tr>
<td>820.130</td>
<td>Device packaging</td>
<td>0</td>
<td>377</td>
<td>5</td>
</tr>
<tr>
<td>820.120</td>
<td>Device labeling</td>
<td>2</td>
<td>271</td>
<td>29</td>
</tr>
<tr>
<td>820.25</td>
<td>Personnel</td>
<td>0</td>
<td>159</td>
<td>2</td>
</tr>
<tr>
<td>820.100</td>
<td>Corrective and preventive action</td>
<td>0</td>
<td>122</td>
<td>7</td>
</tr>
</tbody>
</table>
Recall Challenges

- Understanding the Risk
- Adequate Notification
- Root Cause Analysis
- Corrective and Preventive Actions
- Closing a Recall
- Terminating a Recall
Understanding the Risk

A Health Hazard Evaluation (HHE) is a risk assessment to guide the Center in classifying the recall and determining what actions are needed by the firm and FDA to protect the public health.
21 CFR part 7

- Part 7
  - How to conduct a recall
  - FDA expectation of industry’s actions
  - Provides guidance
    - For manufacturers and distributors
    - On voluntary recalls

- 21 CFR 7.46
  - You are requested to report corrections or removals to your FDA District Recall Coordinator as soon as possible.
21 CFR 7.42 Recall Strategy

- The recall strategy will include the following elements:
  - Depth – level in the distribution chain
  - Public Warning – purpose is to alert the public that the product being recalled presents a serious hazard to health
  - Effectiveness Checks – verifies that all consignees at the recall depth specified have received notification and have taken appropriate action

- The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted
Reporting Requirements

- 21 CFR 806
  - This is a reporting requirement
  - It is not instructions on how to conduct a recall
  - It is not a requirement to conduct a recall

- 21 CFR 806.10(b)
  - Remember, you are required to report within 10 business days after initiating such correction or removal.
Exemptions from Requirements

- 21 CFR 806.1b Exemptions
  1. Changes which improve quality but do not reduce a risk to health or remedy a violation
  2. Market Withdrawals
  3. Routine Servicing
  4. Stock Recoveries
Who Must Report to FDA?

- 21 CFR 806.10(a)
  
  Each device manufacturer or importer shall submit a written report to your FDA district office of any **correction or removal** of a device initiated by such manufacturer or importer if the correction or removal was initiated:

1. To **reduce a risk to health** posed by the device; or

2. To **remedy a violation of the act** caused by the device which may present a risk to health
Required Information

- All information according to 21 CFR 806.10(c)(1-12).

- Business Rule: If any of the required information is unavailable at the time of submission, the reporter must indicate why it is not available and when it will be submitted (21 CFR 806.10(c)(13)).
Reporting Requirements

- 21 CFR 806.10(f)
  - No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 – Medical Device Reporting or 1004 – Repurchase, Repairs, or Replacement of Electronic Products.
21 CFR 806.20

(a) Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under 806.10 shall keep a record of such correction or removal.

(b) Records of corrections and removals not required to be reported to FDA under 806.10 shall contain the information listed in this part.

(4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any follow-ups, and be reviewed and evaluated by a designated person.
Reporting Requirements

- 21 CFR 806.20
- (5) A copy of all communications regarding the correction or removal.
  - c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device.
Tell the FDA

- Your local FDA District Office Recall Coordinator (DRC)
- Foreign manufacturers use the DRC local to their importer/agent
- It’s not just a good idea; it’s the LAW
  - If there is a risk to health, report
  - Within 10 days of initiation
- 21 CFR 806
  - This is reporting.
  - It is NOT instructions on how to conduct a recall.
Mandatory Recalls

21 CFR 810
- Cease distribution and notification order

- There is a reasonable probability that the medical device will cause serious adverse health consequences or death.
  - 21 U.S.C. 360h(e)
  - FD&C § 518(e)
Distinguishing Medical Device Recalls from Enhancements

The guidance is intended to:

- Clarify when a change to a device constitutes a medical device recall
- Distinguish those instances from device enhancements
- Clarify reporting requirements under 21 CFR Part 806
Factors that do not apply

This guidance does not address nor apply to:

- whether a new premarket submission is required
- radiation-emitting electronic product defects or failures to comply with radiation safety performance standards contained in 21 CFR Parts 1020 to 1050
- methodologies for risk management or risk assessment
As defined at 21 CFR 7.3(g), “recall means a firm's removal or correction of a marketed device that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.”

- Recall does not include routine servicing.
- Recall also does not include an enhancement, as defined by this guidance.
Enhancement Definition

A device enhancement is

- (1) a change to improve the performance or quality of a device; that is
- (2) not a change to remedy a violation of the FD&C Act.

Device enhancements include, but are not limited to, changes designed to better meet the needs of the user, changes to make the device easier to manufacture, changes to improve the device’s safety or performance, and changes to the appearance of the device that do not affect its use.
What is the Violation?

- The key factor in distinguishing a medical device recall from an enhancement is the existence of a violation of the FD&C Act.
Differentiating Violative Devices from Non-Violative Devices

- Are the changes intended to resolve a failure to meet specifications or failure of the device to perform as intended?
- Is the labeling for the device to which you are considering making changes false or misleading, does it fail to have adequate directions for use, or does it include indications for use that are not cleared?
- Are you otherwise out of compliance with the FD&C Act or FDA regulations?
Comparison Example

- An in vitro diagnostics (IVD) device firm markets a test to detect the level of a specific antigen in blood.

- The device represents 95% sensitivity to the specific antigen.
Comparison Example (Recall)

- Two years after initial marketing, the firm determines that the device *sensitivity* to the specific antigen, as manufactured, has *decreased to 90%*; thus, not meeting performance specifications and making the device violative.

- As a result, the firm modifies the product in the field to “improve” the sensitivity from 90% to 95%.

- Because the firm’s actions are returning the product to the quality it was represented to possess, FDA would generally consider these actions a recall.
An in vitro diagnostics (IVD) device firm markets a test to detect the level of a specific antigen in blood.

The device represents 95% sensitivity to the specific antigen.
Two years after initial marketing, the firm modifies the product to improve the sensitivity to the antigen from 95% to 98%.

This modification is determined to be an improvement to the safety and effectiveness of the device, and is determined to be unrelated to any known device violation.

FDA would generally regard this action as a device enhancement, although it may require a regulatory submission.
Medical device enhancements do not require the submission of an 806 report.
Once a determination has been made, whether the change represents a medical device recall or enhancement, additional regulatory obligations should be considered.
Important Factors

Reiterate: The guidance is not introducing anything new and only providing more clarity of FDA expectations. Note that this guidance…

- seeks to address concerns that firms may have about making enhancements
- applies to medical devices regulated by CDRH, whether or not they require or are exempt from premarket review
- does not alter current expectations regarding medical device recalls
Summary

- CDRH encourages firms to apply continuous process improvement
  - Enable product improvements for non-violative products
  - Reduce unnecessary paperwork and administrative workload

- The final guidance provides clarity to regulatory terms and definitions specific to medical device recalls and enhancements
Summary

- Correctly categorizing medical device recalls and medical device enhancements
  - Amplifies the likelihood that firms will appropriately determine when to report a recall
  - Fosters the likelihood that FDA would concur with industry decisions regarding device enhancements.
Summary

- Non-Violative devices may be enhanced
- Violative device may result in recalls
- No changes or impact to existing compliance program, CFRs, performance standards, or 510(k) requirements.
- Investigators should request to see any records for device enhancements, correction and removals, field notifications, etc.
- Please contact CDRH if you are unsure about whether something is reportable.
Recall Communications

- Communications with other stakeholders
  - Communications with patients and providers
  - Updating procedures according to new health risk information
  - User notifications of new information – recall or not?
  - Press releases
  - Communications with the business community
Recall Communications

Sec. 7.49 Recall communications.

(a) *General.* A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:
Recall Communications

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.
Recall Communications

- The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication.
Recall Communications

- **Responsibility of recipient.** Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.
Important Factors to Consider

- Get it right the first time
- Work with the FDA
- Title – **URGENT MEDICAL DEVICE RECALL**
- Describe the risk to patients
- Post for visibility
Common Mistakes

- Engineering risk instead of public health risk
- Multiple revisions
- Inappropriate Information
  - Qualification data
  - Promotional materials
  - Other statements that may detract from the message
References and Websites

- 21 CFR Parts 7, 806, 810, and 820

- [www.fda.gov](http://www.fda.gov)
  - CDRH Learn: Recalls video and slide shows
  - Recalls & Safety Alerts – contains industry guidance
    - [http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm](http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm) (CDRH recalls site)

- Federal Register - June 16, 1978 - Part 7
- FDA Regulatory Procedures Manual, Chapter 7
A gift from your government
Questions?

DICE
CDRHQuestions@fda.hhs.gov

CDRH Recall Branch
CDRHRRecallGroup@fda.hhs.gov

My contact information:
Ronny.Brown@fda.hhs.gov