Corrections and Removals

The Context
Device manufacturers may need to resolve a problem by modifying a device already shipped. In general, the manufacturer reports these modifications to FDA, although the regulation identifies some reporting exemptions. The regulation requires the manufacturer to report within 10 days of initiating the action.

The Warning Letter
On August 3, 2016, FDA sent a Warning Letter to Spiegelberg Gmbh & Co. KG, a manufacturer of intercranial pressure monitoring products, located Hamburg, Germany. The Warning Letter was the result of an FDA inspection.

The Issue Cited
The Warning Letter cited a failure to submit a written correction or removal report to FDA as required by 21 CFR §806.10.

The citation says, "[Y]our firm performed a field correction and removal in 12/2009-01/2010 involving ICP Probe 3PN and ICP Probe 3PS, due to a complaint reporting shrinkage of the probe air-pouch resulting in false high ICP readings in the lower measuring ranges of 0-20 mmHg. The air-pouch production procedure was then revised … A letter was sent to customers notifying them of the issue and instructing them to return the affected devices."

The firm responded to the inspection result, and FDA concluded that the response was not adequate. "Your firm stated that they 'thought that this information should have been disseminated by Aesculap Inc., and Aesculap Inc. decided not to do so'. As of April 4th, there is no record of Spiegelberg Gmbh & Co. KG submitting a report of correction or removal to FDA."

The Requirement
The Corrections and Removal regulation, in §806.10, requires a written report for a correction or removal initiated to reduce a risk to health or to remedy a violation of FD&CA that may present a risk to health.

Recommendations
Every time your company notifies a customer of a problem and promises to fix it, that action is subject to the corrections and removals regulation.

While Part 806 does not require a written procedure, best practices indicate that it would be in the company's best interest.

In the procedure, include the following points:

- Review all customer communication related to device problems and their fixes. This includes changes to the device itself, its packaging, or its labeling. In addition, this includes any software downloads, such as bug fixes, that address problems.

- Classify each communication as “reduce a risk to health”, remedy a violation of the FD&CA”, both, or neither.
- Unless the classification is neither, the default decision should be to report.
- Apply the four criteria in §806.1(b) to determine if an exemption applies.
- If the decision is to report, then report on time and include the information in §806.10(c).
- If the decision is not to report, then create the records required by §806.20(b).

Recall

FDA will review the report to determine if it is a recall and, if so, which class. Become familiar with the requirements in Part 7 to help prepare for any subsequent recall activity.