FDANEWS PRESENTS THE

16TH ANNUAL

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APRIL 23-25, 2019

MARRIOTT BETHESDA NORTH HOTEL & CONFERENCE CENTER • BETHESDA, MD

Panel Discussion: Medical Device Recalls or Product Enhancement? Understanding When to Submit a Part 806 Report

Moderator: **Steve Niedelman**, Lead Quality Systems and Compliance Consultant, King & Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations

Panelists:

- **Pamela Furman Forrest**, Partner, Covington & Burling
- **Chris Harvey**, Director- Recall Solutions, Stericycle

Understanding When to Submit a Part 806 Report

April 24, 2019

Pamela Forrest, Partner
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Overview

Regulatory and Policy Framework Governing Recalls

	Statute	**Regulations**
Voluntary recalls		21 C.F.R. Part 7*
Mandatory device recalls	FDCA § 518(e)	21 C.F.R. Part 810
Reports of corrections and removals	FDCA § 519(g)	21 C.F.R. Part 806

*Although published in the C.F.R, Part 7 is agency guidance

Part 7

- 21 C.F.R. §§ 7.40-7.59, *Guidance on Policy, Procedures and Industry Responsibilities*
- Part 7 is guidance, not law
  - Recalls conducted pursuant to Part 7 are “voluntary”
- Part 7 defines key recall-related terms and provides guidance on how to conduct a recall
  - Defines what is/what is not a recall
  - Defines classifications of recalls
  - Provides instructions on how to conduct a recall
  - Applies to all FDA-regulated products

21 C.F.R. Part 806 – Reports of Corrections and Removals

- Part 806 only applies to medical devices
- Part 806 has the force of law
- Part 806 sets out the circumstances under which "voluntary" recalls must be reported to FDA

- The requirement to report certain corrections and removals was added to the FDCA in 1990 because Congress was concerned that firms were conducting voluntary recalls without notifying FDA, and that mandatory reporting of certain recalls was necessary to enable FDA to take prompt action against dangerous devices

Corrections and Removals: Definitions

- Correction: repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product *without its physical removal* to some other location (21 C.F.R. §§ 7.3(h), 806.2(d))
- Removal: *physical removal of a device* from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection (21 C.F.R. § 806.2(j))

- Recall: firm's *removal or correction* of a marketed product that the FDA considers to be *in violation of the FDCA* and against which FDA would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery. (21 C.F.R. § 7.3(g))

When to Report under Part 806

Under Part 806, Reportability Turns on "Risk to Health"

- Must report any correction or removal of a device if action was initiated to:
  - Reduce a risk to health posed by the device, or
  - Remedy a violation of the FDCA caused by the device which may present a risk to health

- Report must be submitted within 10 working days of initiating the correction or removal
  - FDA interprets "initiating" the correction or removal as the date a firm makes the decision to initiate a field action (62 FR 27188)

21 C.F.R. § 806.10

Risk to Health

- Risk to health:
  - A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death, or
  - That use of, or exposure to, the product may cause:
    - temporary or medically reversible adverse health consequences, or
    - an outcome where the probability of serious adverse health consequences is remote

(21 C.F.R. § 806.2(k))

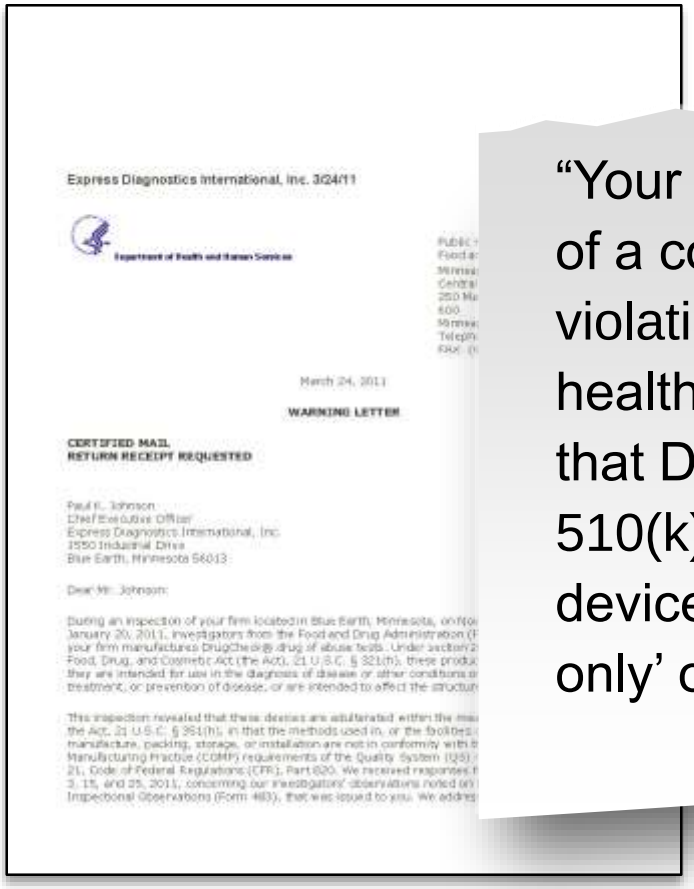
- Reports are required for Class I and II recalls, but not for Class III recalls (62 FR 27184)
  - The definition of “risk to health” in Part 806 aligns with the definitions of Class I and Class II recalls in Part 7

Reportability Considerations

- Factors to consider in determining risk to health:
  - Health Hazard Evaluation
  - MDR reporting history
  - FDA's classification of similar recalls
  - Enforcement activity

- FDA interprets "risk to health" very conservatively

Warning Letter Example



Express Diagnostics International, Inc. 3/24/11

March 24, 2011

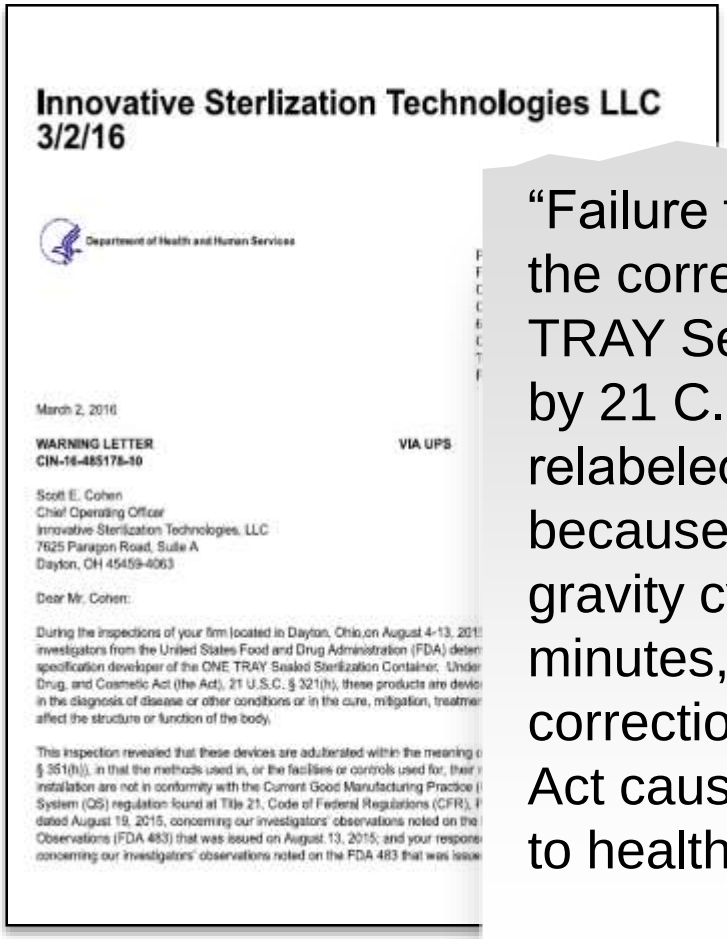
WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

"Your firm failed to submit a written report to FDA of a correction or removal…initiated to remedy a violation of the Act which might present a risk to health….Specifically,…your firm notified customers that DrugCheck Cup testing devices…did not have 510(k) clearance. To correct the problem, devices…were to be re-labeled as 'forensic use only' or replaced with 'dip devices.'"

Warning Letter to Express Diagnostics International, Inc., March 24, 2011

Warning Letter Example



Innovative Sterlization Technologies LLC
3/2/16

Department of Health and Human Services

March 2, 2016

WARNING LETTER **VIA UPS**
CIN-16-485178-10

Scott E. Cohen
Chief Operating Officer
Innovative Sterilization Technologies, LLC
7625 Paragon Road, Suite A
Dayton, OH 45459-4063

Dear Mr. Cohen:

During the inspections of your firm located in Dayton, Ohio,on August 4-13, 201
investigators from the United States Food and Drug Administration (FDA) deter
specification developer of the ONE TRAY Sealed Sterilization Container. Under
Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devic
in the diagnosis of disease or other conditions or in the cure, mitigation, treatmer
affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning
§ 351(h)), in that the methods used in, or the facilities or controls used for, their
installation are not in conformity with the Current Good Manufacturing Practice
System (QS) regulation found at Title 21, Code of Federal Regulations (CFR),
dated August 19, 2015, concerning our investigators' observations noted on the
Observations (FDA 483) that was issued on August 13, 2015; and your respons
concerning our investigators' observations noted on the FDA 483 that was issue

"Failure to submit a written report to FDA regarding the correction that your firm made to the ONE TRAY Sealed Sterilization Container, as required by 21 C.F.R. Part 806.10. In January of 2014, you relabeled all customers' One Tray devices, because there was a typo on the labeling for the gravity cycle. The cycle should state 17-34 minutes, but it stated 10-34 minutes. This correction was initiated to remedy a violation of the Act caused by the device which may present a risk to health. "

Warning Letter to Innovative Sterilization Technologies LLC, March 2, 2016

Actions Exempt from Reporting Under Part 806

- On October 15, 2014, FDA issued a final guidance entitled "Distinguishing Medical Device Recalls from Medical Device Enhancements"
  - "Enhancement" defined as (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 or associated regulations enforced by FDA
  - Product enhancements may include changes designed to better meet the needs of the user, changes to make the product easier to manufacture, and changes to the appearance of the device that do not affect its use
  - Changes made to improve a level of safety performance that was known, predicted, and stable at the time the device was cleared or approved do not typically mean that the underlying product was violative

FDA's Guidance on Recalls and Enhancements

- "FDA generally considers devices that fail to meet specifications and devices that fail to perform as intended to be of a quality below what they purport or are represented to possess, which would render them adulterated"

- "An increase in overall failure rate, increase in a single failure mode rate, or the identification of a new failure mode may suggest a failure of the device to perform as represented. A change to the marketed device to address a failure to perform as represented, including a failure to perform to represented specifications, would generally constitute a medical device recall."

Actions Exempt from Reporting Under Part 806

- Market Withdrawal: correction or removal of a distributed product which involves *a minor violation that would not be subject to legal action by FDA* or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. (21 C.F.R. § 806.2(i))
  - Example: A firm decides to remove its examination gloves from the market due to an incorrect address on the device label. This is a minor violation against which FDA generally would not initiate legal action.

- The line between market withdrawal and Class III recall is often unclear
  - A Class II recall is "a situation where use of, or exposure to, a violative product is not likely to cause adverse health consequences." (21 C.F.R. § 7.3(m)(3))

Actions Exempt from Reporting Under Part 806

- Stock Recovery: correction or removal of a product that:
  - Has not been marketed or
  - Has not left the direct control of the manufacturer

  i.e., the product is located on premises owned by, or under the control of, the firm, and no portion of the lot has been released for sale or use (21 C.F.R. § 806.2(m))

- FDA interprets "under the control of" very conservatively
- The second half of the definition is often overlooked
  - An action is not a Stock Recovery if a portion of the affected lot or lots has been distributed

Actions Exempt from Reporting Under Part 806

- Routine servicing: regularly scheduled maintenance of a medical device, including the replacement of parts at the end of their normal life expectancy (21 C.F.R. § 806.2(l))
  - Does not include: repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device

Cybersecurity Related Actions

- Routine updates and patches – to remediate vulnerabilities associated with "controlled risk" – generally considered to be enhancements, and thus usually do not require a Part 806 report
- Actions to remediate vulnerabilities associated with an "uncontrolled risk" are exempt from Part 806 reporting if:
  - There are no known serious adverse events or deaths associated with the vulnerability
  - Within 30 days, the manufacturer communicates the vulnerability to customers and users, identifies interim compensating controls, and develops a remediation plan
  - Within 60 days, the manufacturer fixes the vulnerability, validates the change, and distributes the deployable fix to its customers and user community
  - The manufacturer actively participates as a member of an Information Sharing and Analysis Organization (ISAO) that shares vulnerabilities and threats that impact medical devices
- (Guidance for Industry and FDA Staff, "Postmarket Management of Cybersecurity in Medical Devices" (Dec. 2016))

Avoid “Back Door” or “Silent” Recalls

- The problem:
  - Firms sometimes undertake actions in the field without realizing these actions are “corrections” or “removals” that must be analyzed for reportability under Part 806
  - FDA may view such actions as “back-door” or “silent” recalls

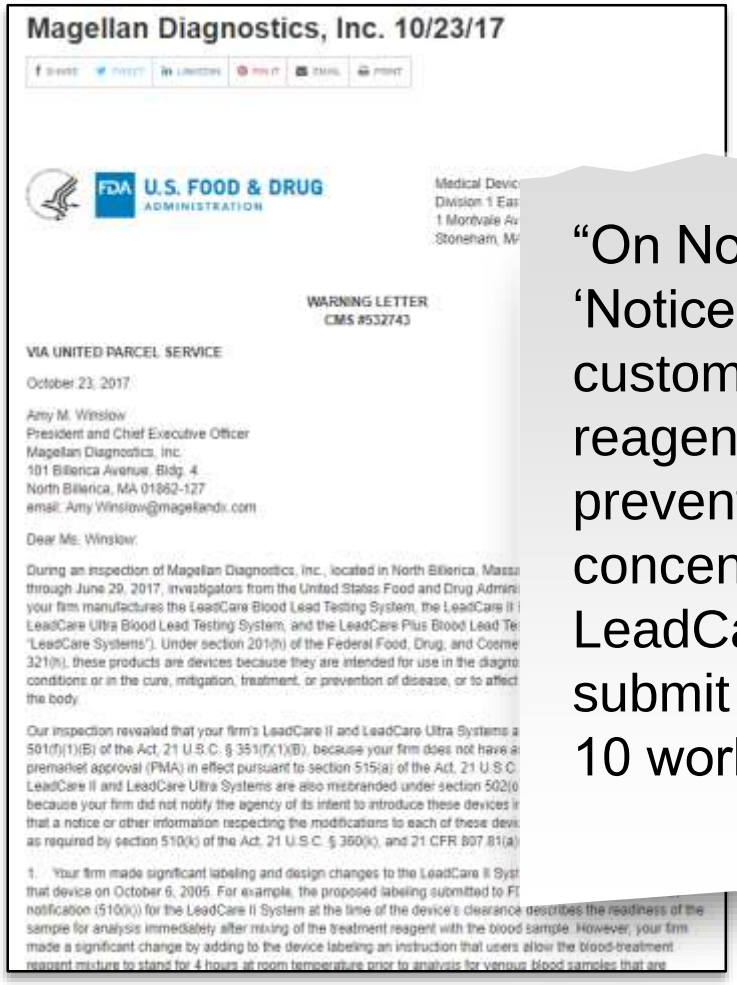
Common Fact Patterns

- Combining a product “upgrade” with a correction/removal
  - Particularly common with software upgrades
- Distributing a “market bulletin” or “technical advisory”
  - Informing customers of recent device problems and advising them of techniques that should be used to help prevent those problems
- Deploying sales representatives to inspect devices in the field to determine whether a known systemic problem is present
- Applying corrections, including inspection of product, during routine maintenance services

Common Fact Patterns (con't)

- Applying corrections to product when complaint is received without systematically removing the potentially defective devices from the field
- "Fix on Fail" activities that involve known, continuing failure modes that are repaired only upon failure
- Addressing only product from a lot that has not yet shipped and ignoring product that has left a company's control
- Exchanging defective or potentially defective product with a corrected device (or replacement with next generation device)

Warning Letter Example: Customer Letter



Magellan Diagnostics, Inc. 10/23/17

U.S. FOOD & DRUG ADMINISTRATION

WARNING LETTER
CMS #532743

VIA UNITED PARCEL SERVICE

October 23, 2017

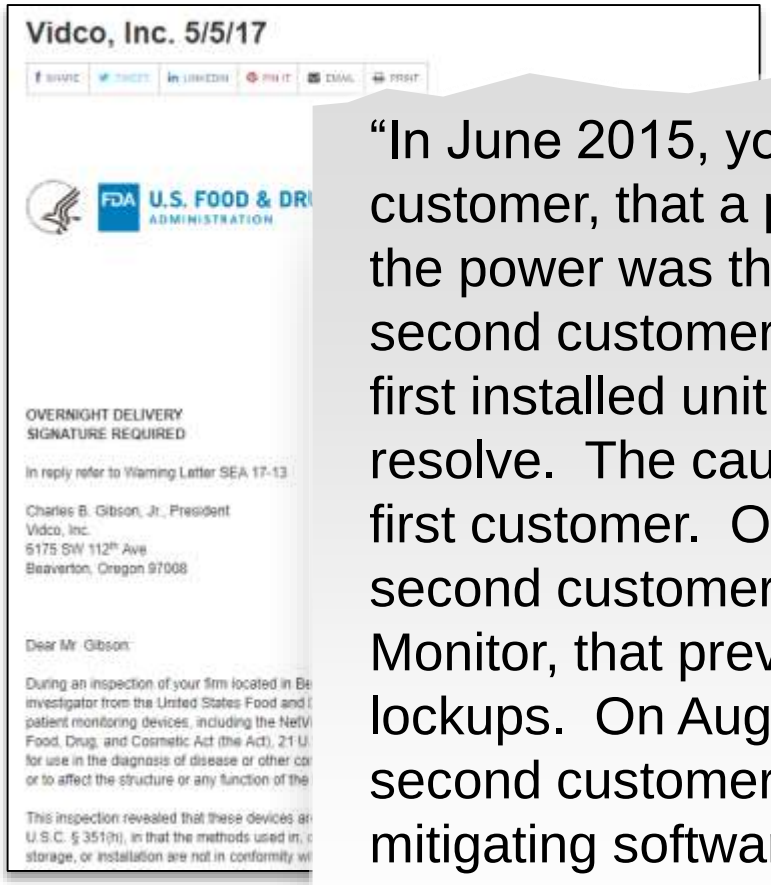
Amy M. Winslow
President and Chief Executive Officer
Magellan Diagnostics, Inc.
101 Billerica Avenue, Bldg. 4
North Billerica, MA 01862-127
email: Amy.Winslow@magellandx.com

Dear Ms. Winslow:

"On November 24, 2014, your firm sent a 'Notice to Customers' letter instructing customers to incubate the blood-treatment reagent mixture for at least twenty-four hours to prevent underestimation of the lead concentration of blood samples for the LeadCare Ultra System. Your firm did not submit a report of a correction or removal within 10 working days of initiating this action."

Warning Letter to Magellan Diagnostics, Inc., October 23, 2017

Warning Letter Example: Correcting Only Complaints



Vidco, Inc. 5/5/17

U.S. FOOD & DR
ADMINISTRATION

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 17-13

Charles B. Gibson, Jr., President
Vidco, Inc.
6175 SW 112th Ave
Beaverton, Oregon 97008

Dear Mr. Gibson:

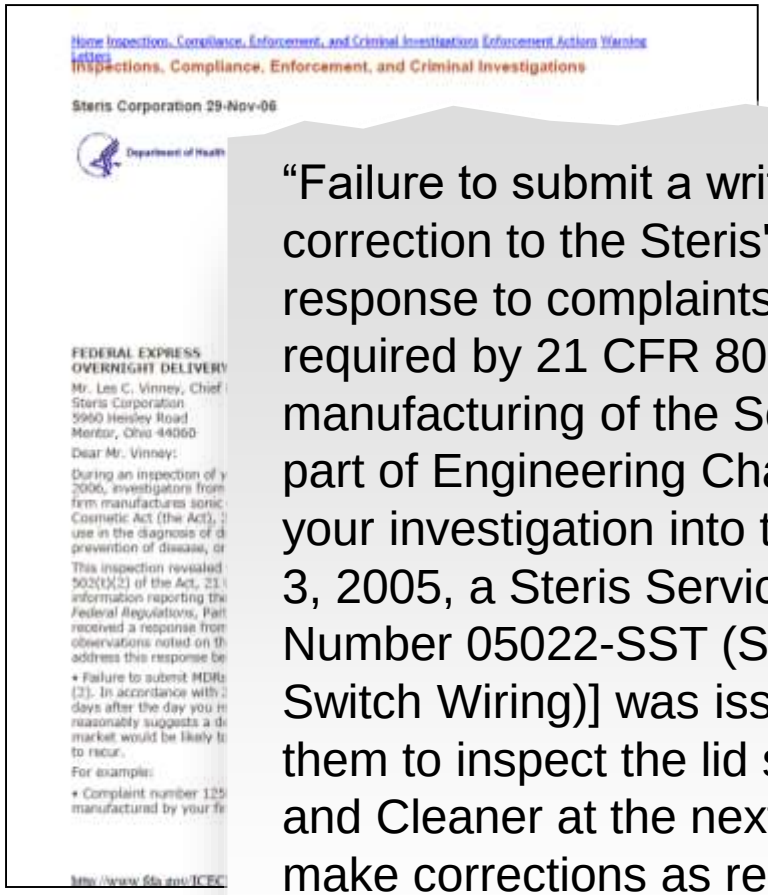
During an inspection of your firm located in Be
investigator from the United States Food and
patient monitoring devices, including the Ne(
Food, Drug, and Cosmetic Act (the Act), 21 U.
for use in the diagnosis of disease or other co
or to affect the structure or any function of the

This inspection revealed that these devices ar
U.S.C. § 351(h), in that the methods used in,
storage, or installation are not in conformity wi

"In June 2015, your firm received a complaint, from a customer, that a patient monitor locked up and re-cycling the power was the only way to restart. In July 2015, a second customer with 16 units notified your firm that the first installed unit froze up and had to be powered-off to resolve. The cause was the same as the lock-up at the first customer. On July 18, 2015, your firm shipped the second customer a loaner unit, with corrected Rom Monitor, that prevented continuous traps to prevent lockups. On August 7, 2015, your firm went to the second customer to update all 16 units with interim mitigating software. FDA was not notified of a correction until November 2015."

Warning Letter to Vidco, Inc, May 5, 2017

Warning Letter Example: Correction During Maintenance



Inspections, Compliance, Enforcement, and Criminal Investigations

Steris Corporation 29-Nov-06

FEDERAL EXPRESS
OVERNIGHT DELIVERY

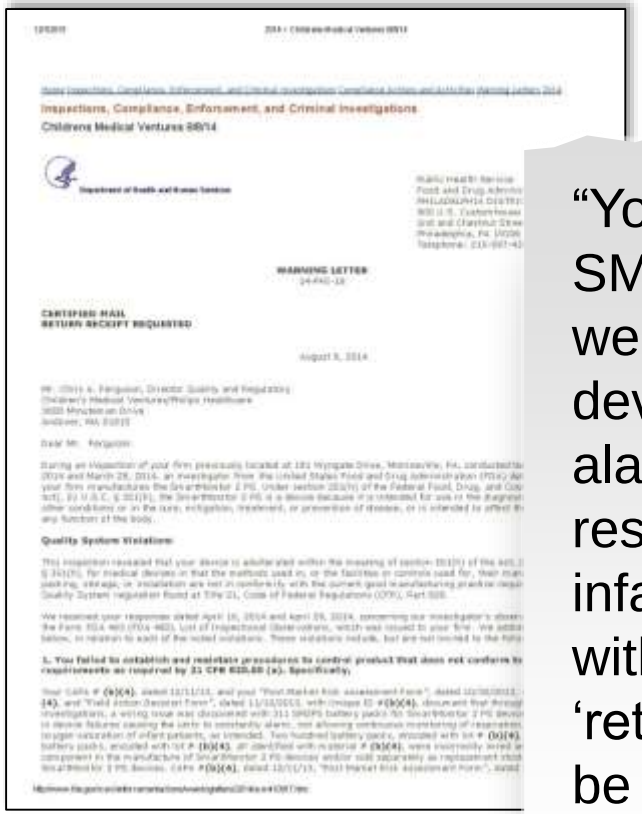
Mr. Les C. Vinney, Chief
Steris Corporation
5960 Heisley Road
Mentor, Ohio 44060

Dear Mr. Vinney:

"Failure to submit a written report to FDA when you initiated a correction to the Steris' Amsco® Sonic Energy Cleaners in response to complaints of fires associated with the units, as required by 21 CFR 806.10. In January 2005, a change to the manufacturing of the Sonic Cleaner was made by your firm, as part of Engineering Change Authorization 054160 in response to your investigation into the complaints discussed above. On June 3, 2005, a Steris Service Tip [MG 1 C–STERIS Service Tips Number 05022-SST (Sonic Energy Systems - Inspection of Lid Switch Wiring)] was issued to your service personnel advising them to inspect the lid switch wiring in the Sonic Energy Console and Cleaner at the next Preventive Maintenance Inspection and make corrections as required of the Sonic Cleaner not having a Preventive Maintenance agreement."

Warning Letter to Steris Corporation, November 29, 2006

Warning Letter Example: Fix on Failure



Inspections, Compliance, Enforcement, and Criminal Investigations

Childrens Medical Ventures 8/8/14

WARNING LETTER

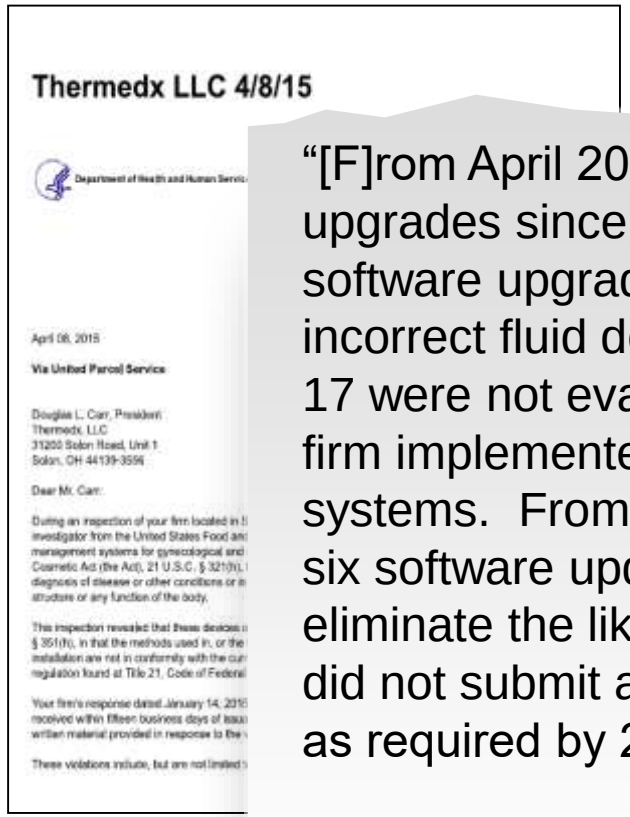
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Quality System Violations

"Your (311) SmartMonitor 2 PS devices and/or SM2PS battery pack replacement components were found to have a wiring issue resulting in device failures causing the units to constantly alarm, not allowing continuous monitoring of respiration, heart rate, and oxygen saturation of infant patients, as intended. Field Change Order with FCO Reference # (b)(4) documents a 'retrofit on failure' field correction is instructed to be performed on all (311) affected units, which was not reported in writing to FDA."

Warning Letter to Children's Medical Ventures/Philips Healthcare, August 8, 2014

Warning Letter Example: Software Updates


Thermedx LLC 4/8/15

April 08, 2015

Via United Parcel Service

Douglas L. Carr, President
Thermedx, LLC
31200 Solon Road, Unit 1
Solon, OH 44139-3596

Dear Mr. Carr:

"[F]rom April 2010 to October 2013, your firm made 21 software upgrades since the release of the fluid management system. The software upgrades included fixes for identified hazards such as incorrect fluid deficit calculation issues. Of the 21 software upgrades, 17 were not evaluated for potential corrections and removals. Your firm implemented all of these software upgrades to all field systems. From April 2011 to April 2014, your firm released at least six software updates to your fluid management system to reduce or eliminate the likelihood of fluid measurement deficiencies. Your firm did not submit a written report to FDA of the correction and removal as required by 21 CFR 806."

Warning Letter to Thermedx LLC, April 8, 2015

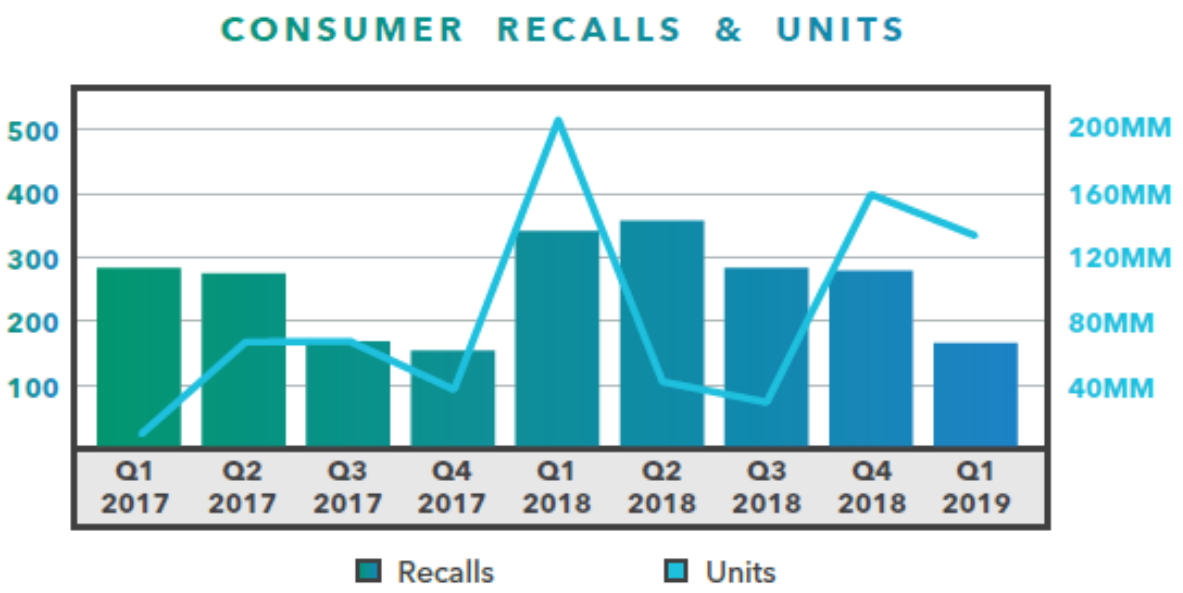
Consequences of Noncompliance

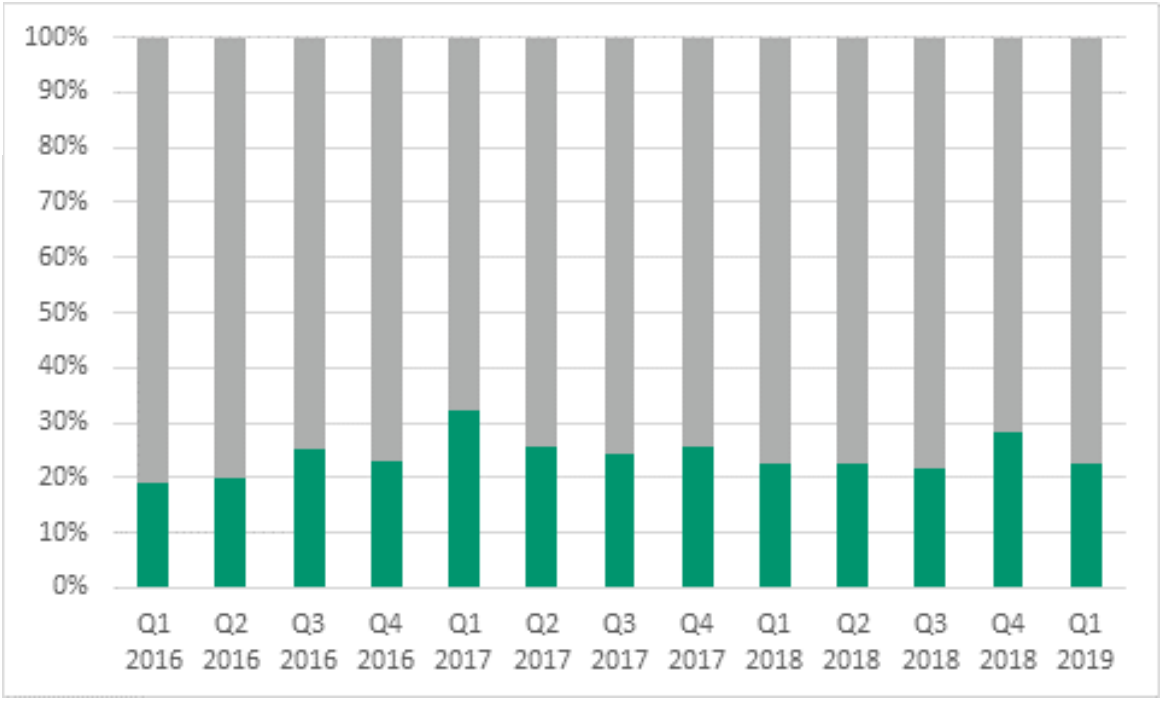
- FDA enforcement action:
  - Failure to comply with Reports of Corrections and Removals requirements "misbrands" the devices in question (21 U.S.C. § 352(t)(2))
  - Introducing an "adulterated" or "misbranded" device into interstate commerce is a "prohibited act" (21 U.S.C. § 331(a))
  - In addition, failure to comply with Reports of Corrections and Removals requirements is an independent "prohibited act" under the FDCA (21 U.S.C. § 331(q))
- Increased product liability risk
- Noncompliances can taint FDA's perception of a manufacturer, creating a climate of distrust

Thank you! Questions?

Medical Device Recalls

Medical Device Trends





Engagement Background

Scoping Call

Communication Package Developed

Logistical Need Determined

Reports/Investigation

Project Strategy Developed

System/Infrastructure Configured

Engagement Background

Reports/Investigation

- Remedy a Violation?
- Risk to Health?
- Marketed/ Distributed?
- Performance Specifications

Recall **LIFE CYCLE**

1

PREPARATION

2

TARGET / CONSIGNEE IDENTIFICATION

3

NOTIFICATION MANAGEMENT

4

RESPONSE MANAGEMENT

5

PRODUCT PROCESSING

6

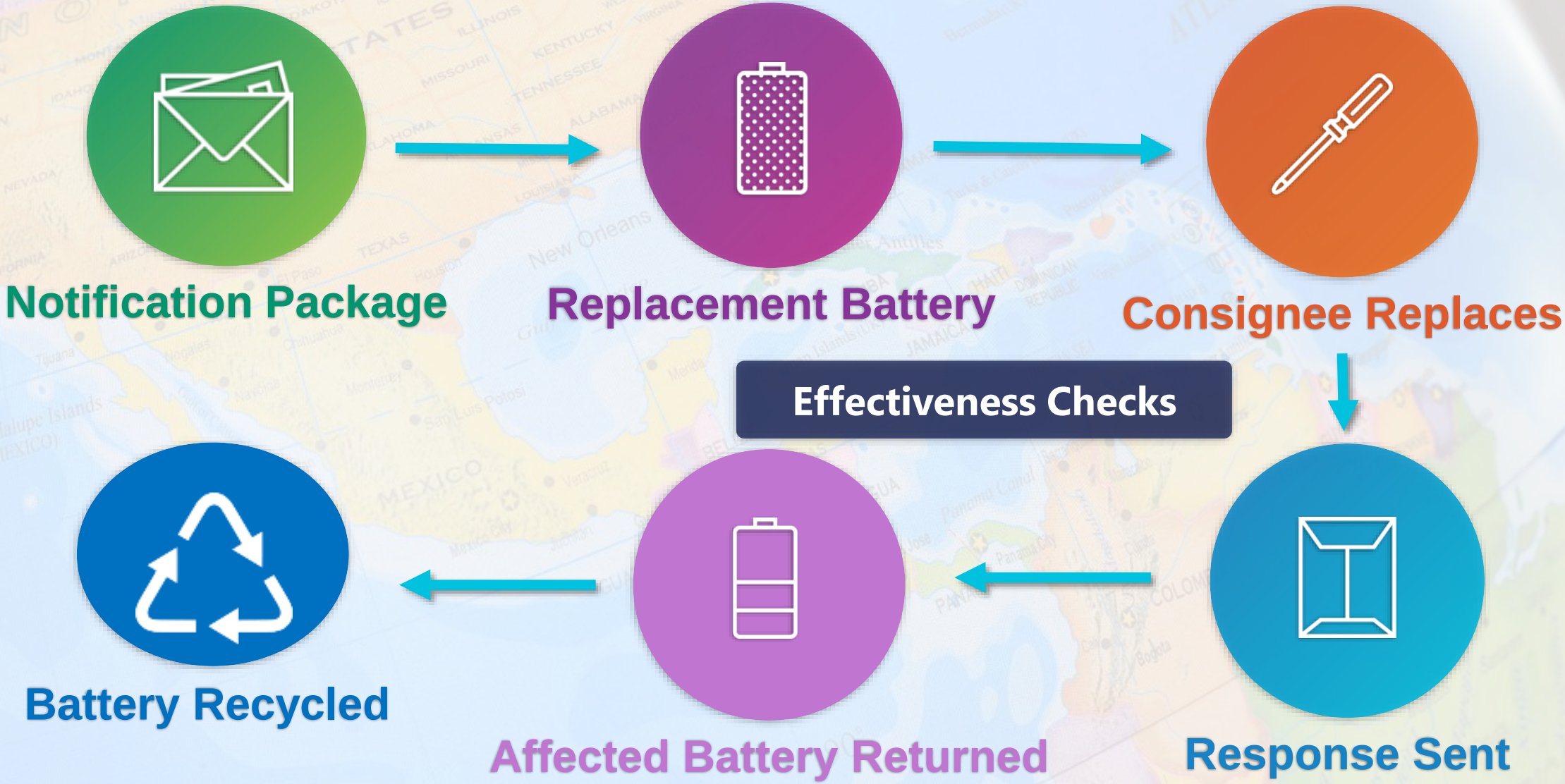
REMEDY MANAGEMENT

7

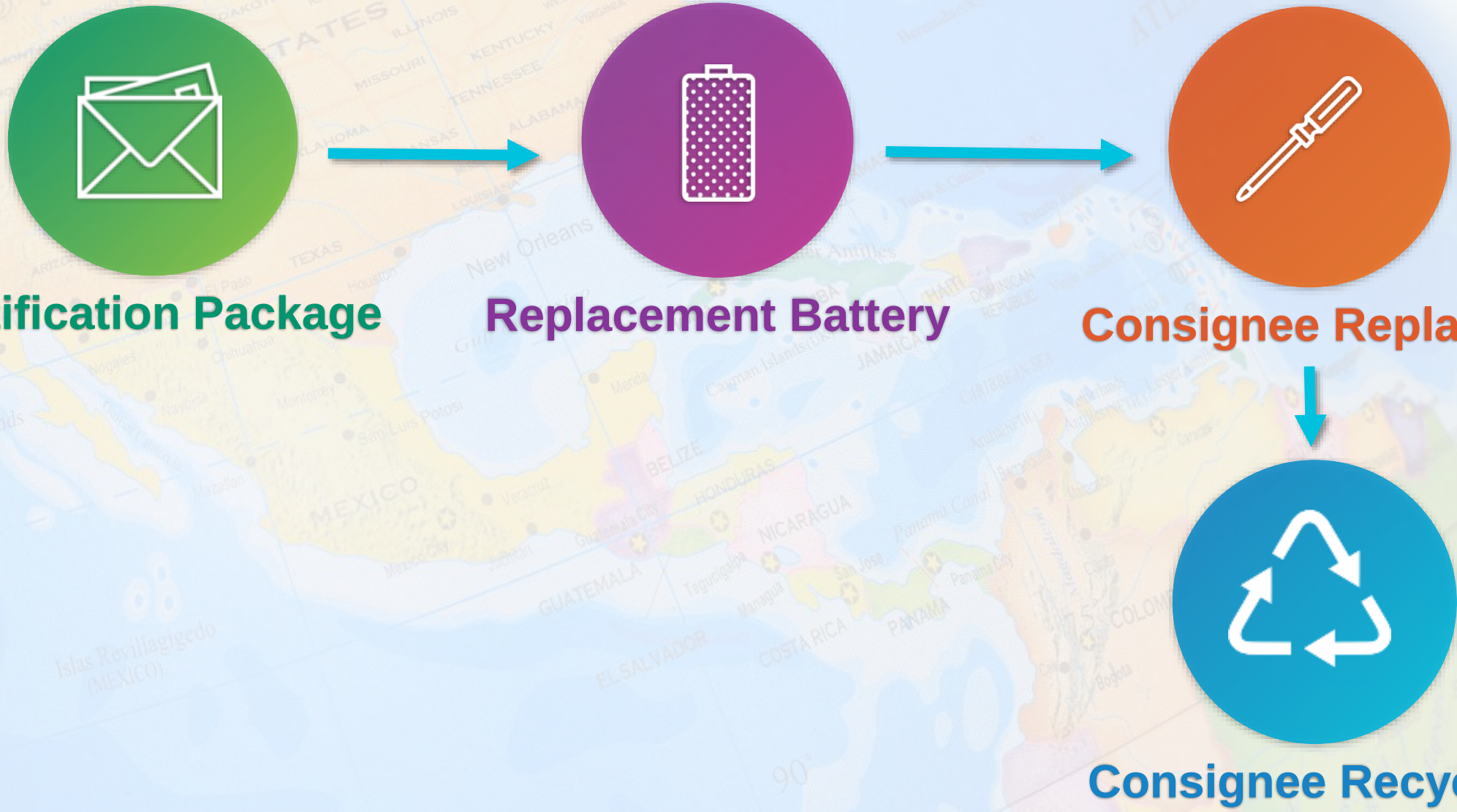
RESOLUTION MANAGEMENT

Recall Platform

Recall Strategy



Enhancement Strategy



Connected Devices

Cybersecurity Vulnerabilities

Non-Recall Scenarios for Discussion…

Safety Alerts
Market Withdrawals
Stock Recoveries
Technical Bulletins
Notifications
Enhancements
Others????

What Is Not a Recall

"Market Withdrawal"

- A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. (21 CFR 7.3(j))

"Stock Recovery"

- A firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm, and no portion of the lot has been released for sale or use. (21 CFR 7.3(k))
  - May include product at logistics and order fulfillment providers